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Stein et al.

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(54) **SPINAL DISTRACTION TOOL FOR LOAD AND POSITION MEASUREMENT**

(75) Inventors: **Marc Stein**, Chandler, AZ (US); **Martin Roche**, Fort Lauderdale, FL (US); **Marc Boillot**, Plantation, FL (US)

(73) Assignee: **Orthosensor Inc**, Dania Beach, FL (US)

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A61B 5/107	(2006.01)
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A61F 2/46	(2006.01)
A61F 2/30	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 5/107*** (2013.01); ***A61B 5/103*** (2013.01); ***A61B 5/1036*** (2013.01); ***A61B 5/1071*** (2013.01); ***A61F 2/4611*** (2013.01); *A61F 2002/30607* (2013.01); *A61F 2002/30616* (2013.01); *A61F 2002/4662* (2013.01); *A61F 2002/4666* (2013.01); *A61F 2002/4667* (2013.01); *A61F 2002/4668* (2013.01); *A61F 2310/00023* (2013.01)

USPC **606/90**; 600/424

(58) **Field of Classification Search**

USPC 606/90, 32; 600/424

See application file for complete search history.

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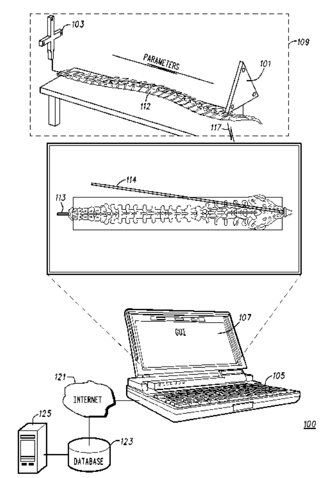
Primary Examiner — Max Hindenburg
Assistant Examiner — Renee Danega

(57) **ABSTRACT**

A spine alignment system is provided to assess load forces on the vertebra in conjunction with overall spinal alignment. The system includes a spine instrument having an electronic assembly and a sensorized head. The sensorized head can be inserted between vertebra and report vertebral conditions such as force, pressure, orientation and edge loading. A GUI is therewith provided to show where the spine instrument is positioned relative to vertebral bodies as the instrument is placed in the inter-vetebral space. The system can distract vertebrae to a first height and measure the load applied by the spine region. The GUI can indicate that the load is outside a predetermined range. The spine region can be distracted to a second height where the load is measured within the predetermined load range.

18 Claims, 11 Drawing Sheets



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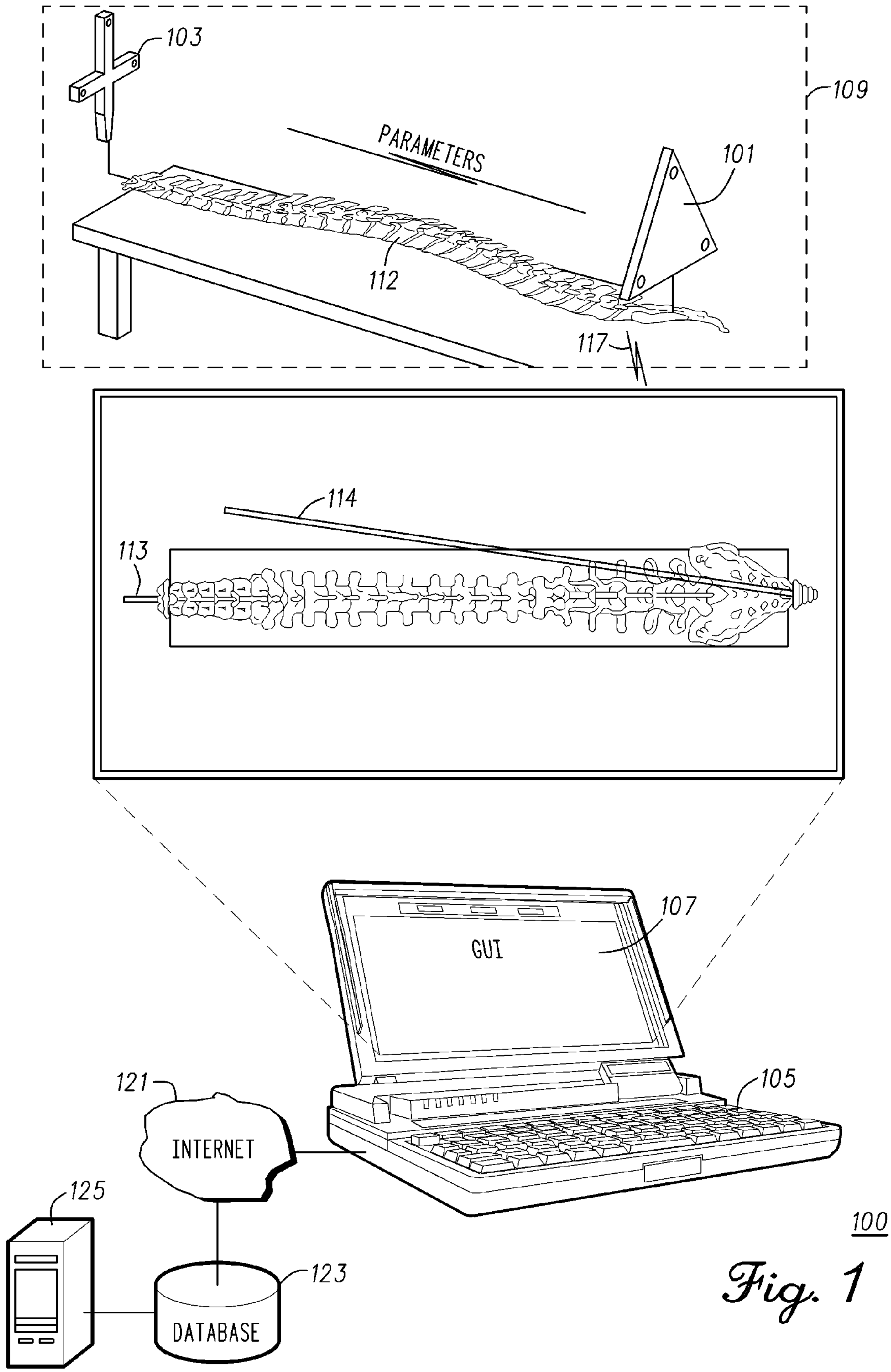

103
109
PARAMETERS
101
112
117
114
113
107
GUI
121
105
INTERNET
125
123
DATABASE
100

Fig. 1

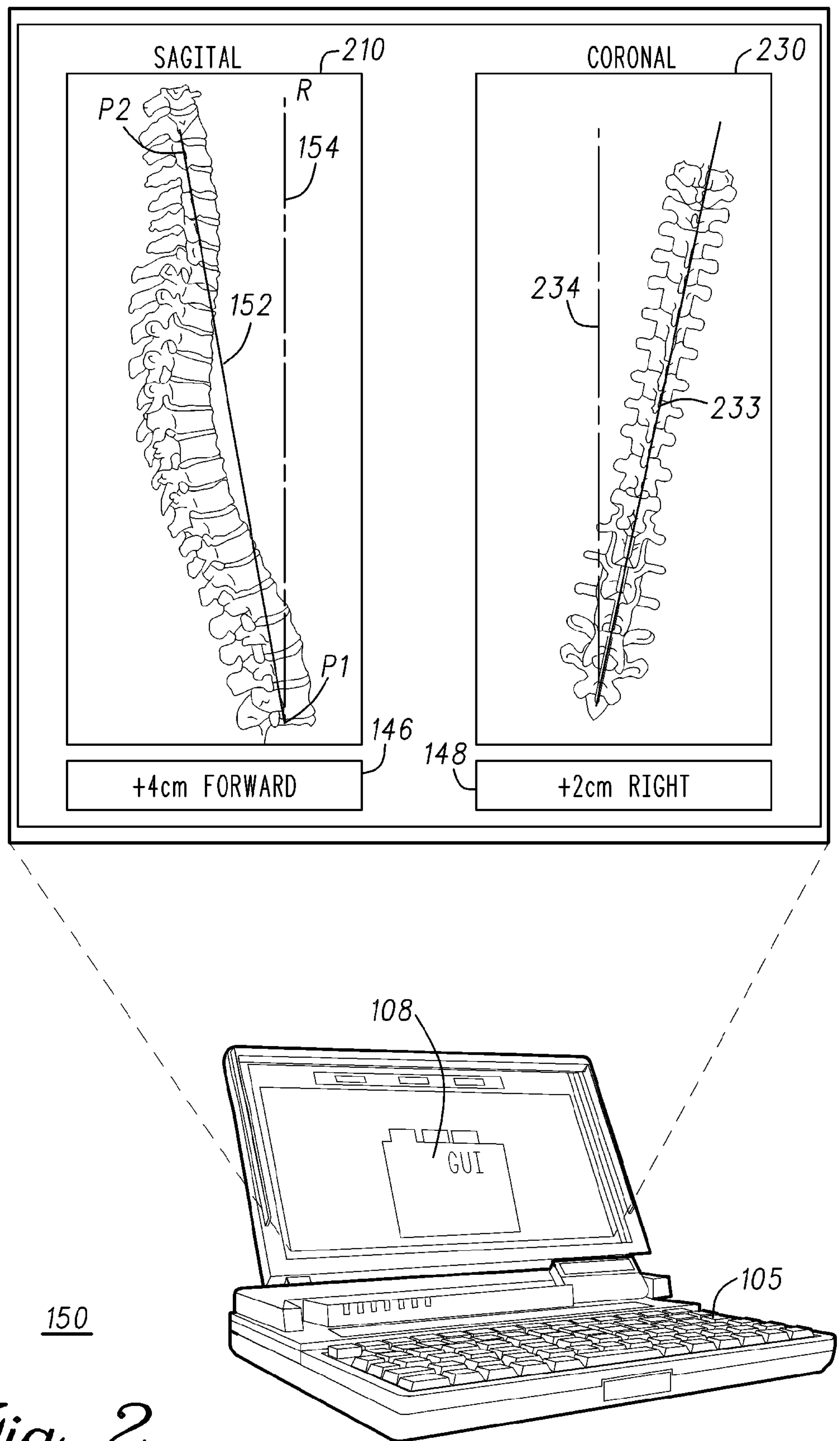

SAGITAL
210
R
P2
154
152
P1
146
+4cm FORWARD
CORONAL
230
234
233
148
+2cm RIGHT
108
GUI
105
150

Fig. 2

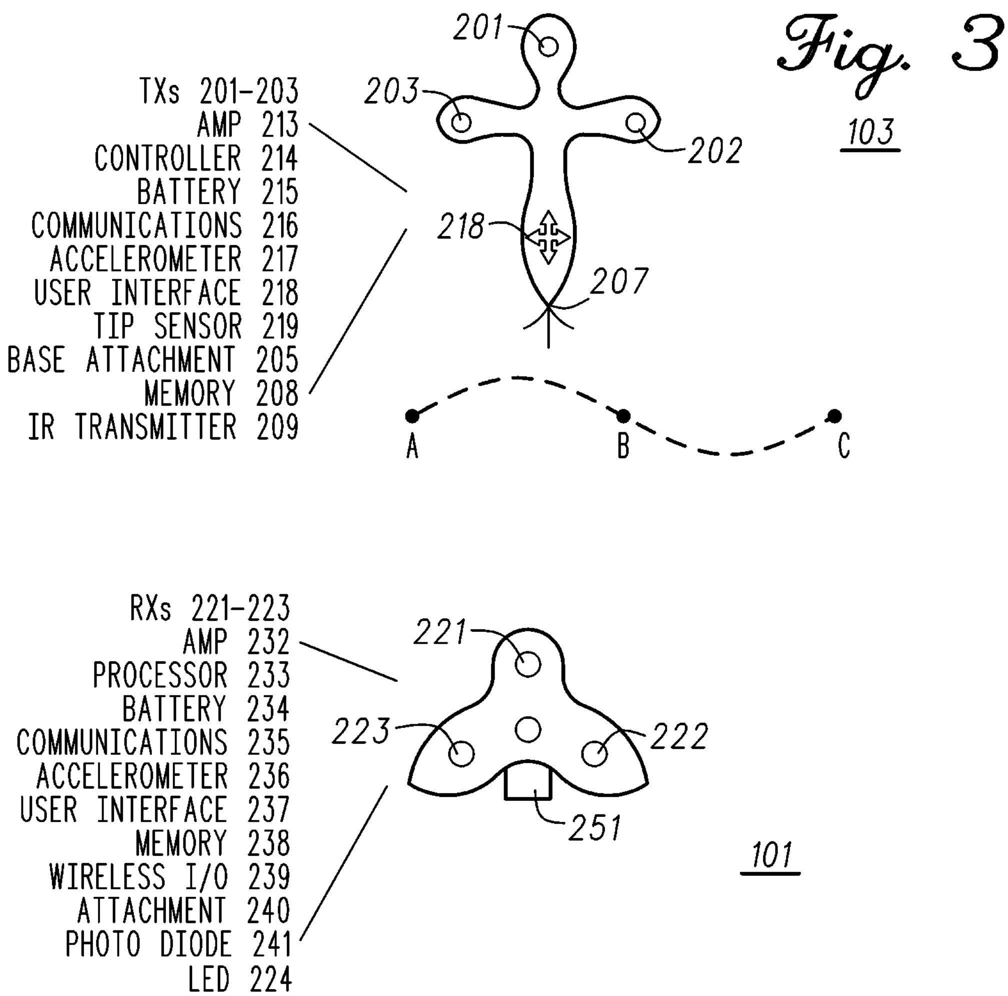


Fig. 3
103
TXs 201-203
AMP 213
CONTROLLER 214
BATTERY 215
COMMUNICATIONS 216
ACCELEROMETER 217
USER INTERFACE 218
TIP SENSOR 219
BASE ATTACHMENT 205
MEMORY 208
IR TRANSMITTER 209
201
202
203
218
207
A
B
C
RXs 221-223
AMP 232
PROCESSOR 233
BATTERY 234
COMMUNICATIONS 235
ACCELEROMETER 236
USER INTERFACE 237
MEMORY 238
WIRELESS I/O 239
ATTACHMENT 240
PHOTO DIODE 241
LED 224
221
222
223
251
101

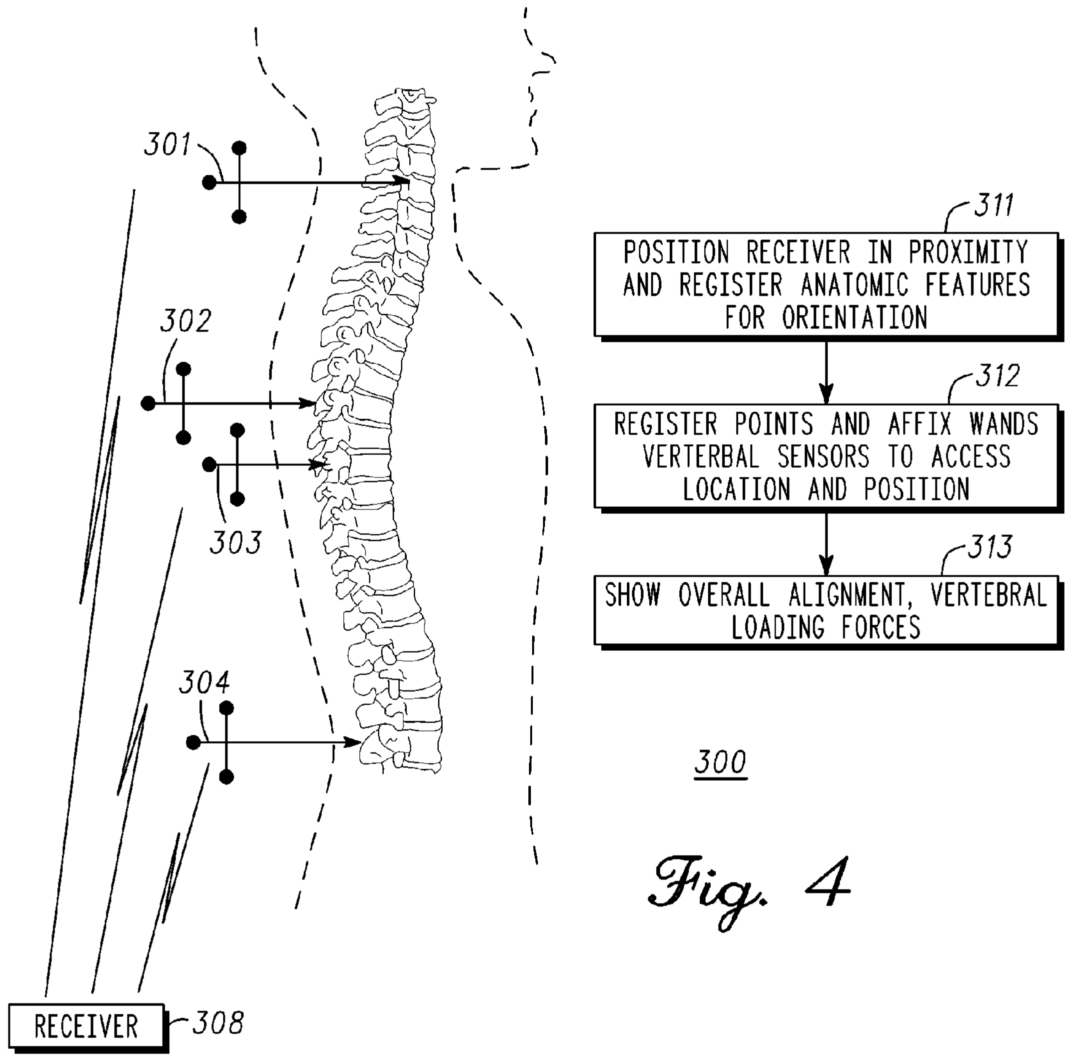


Fig. 4

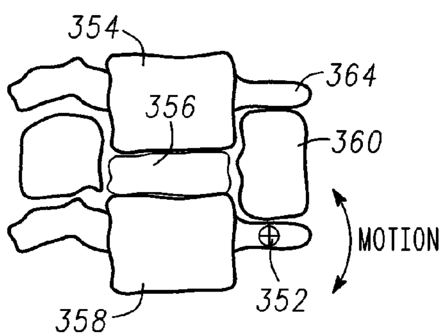
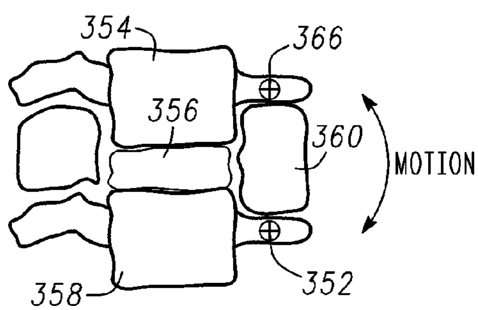


Fig. 5



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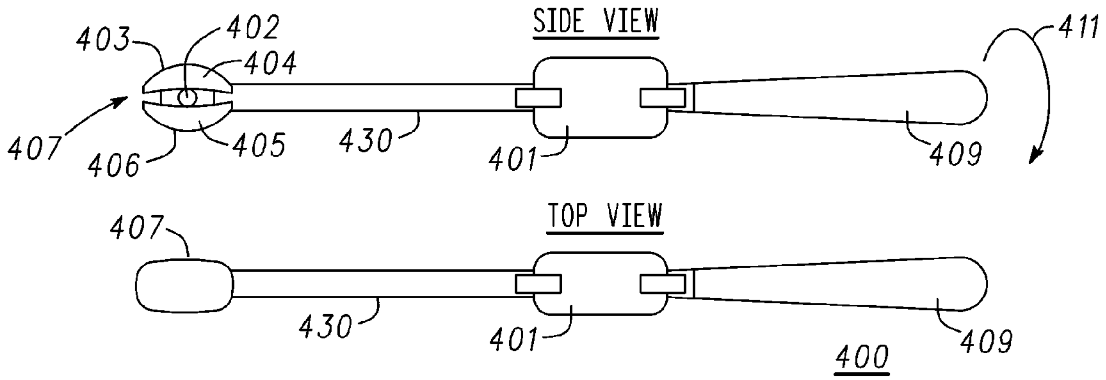


Fig. 7

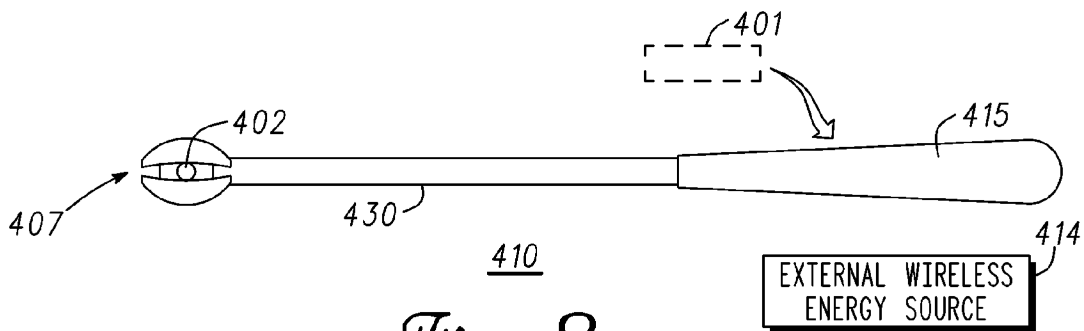


Fig. 8

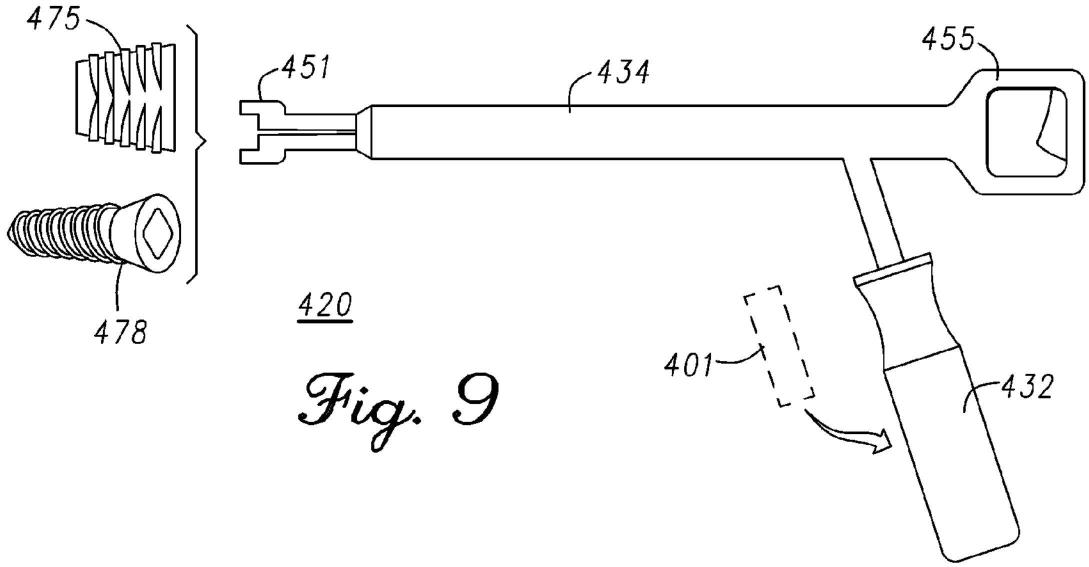


Fig. 9

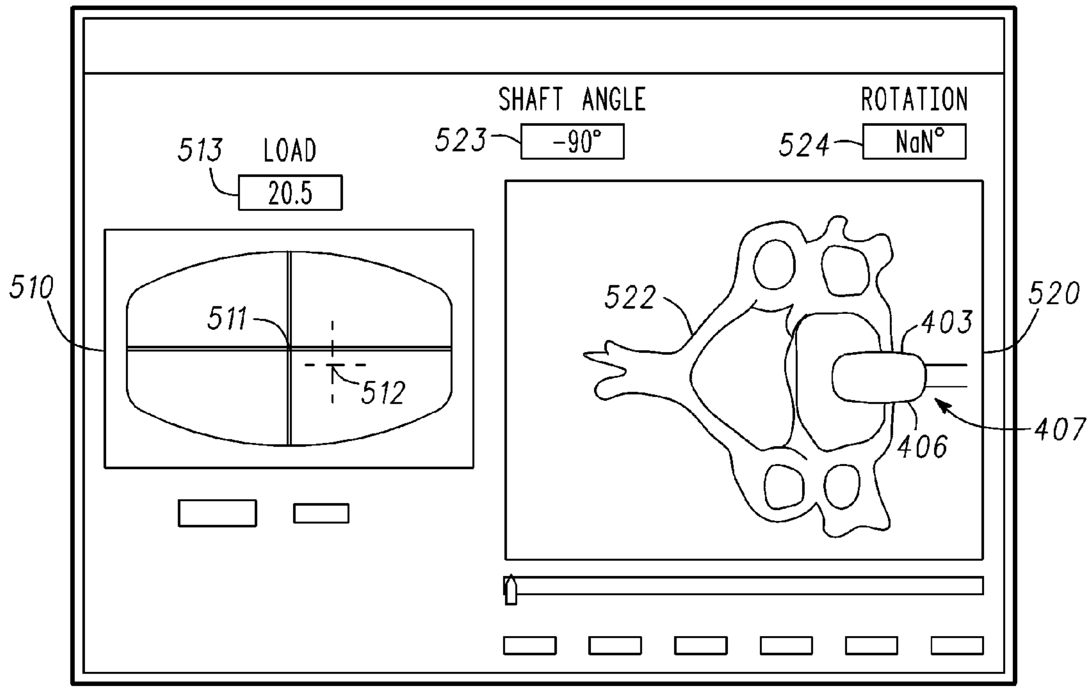


Fig. 11

500

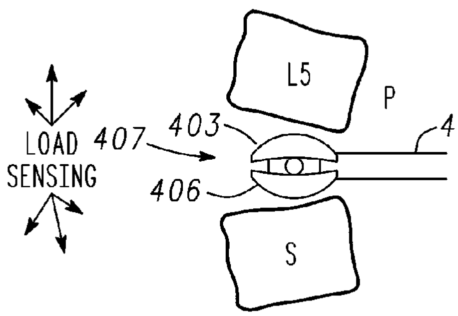


Fig. 10

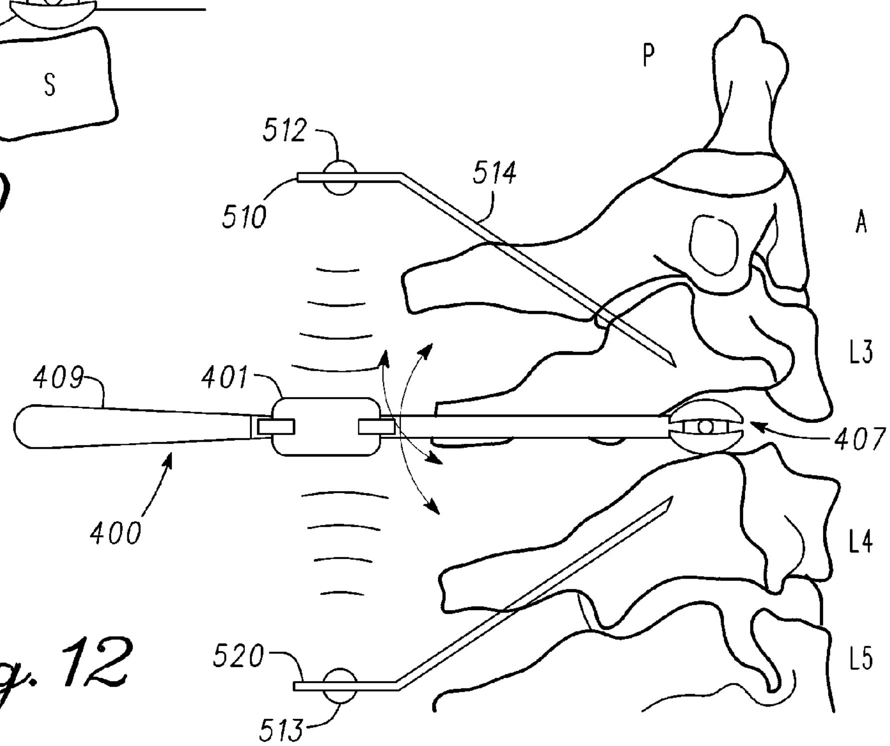


Fig. 12

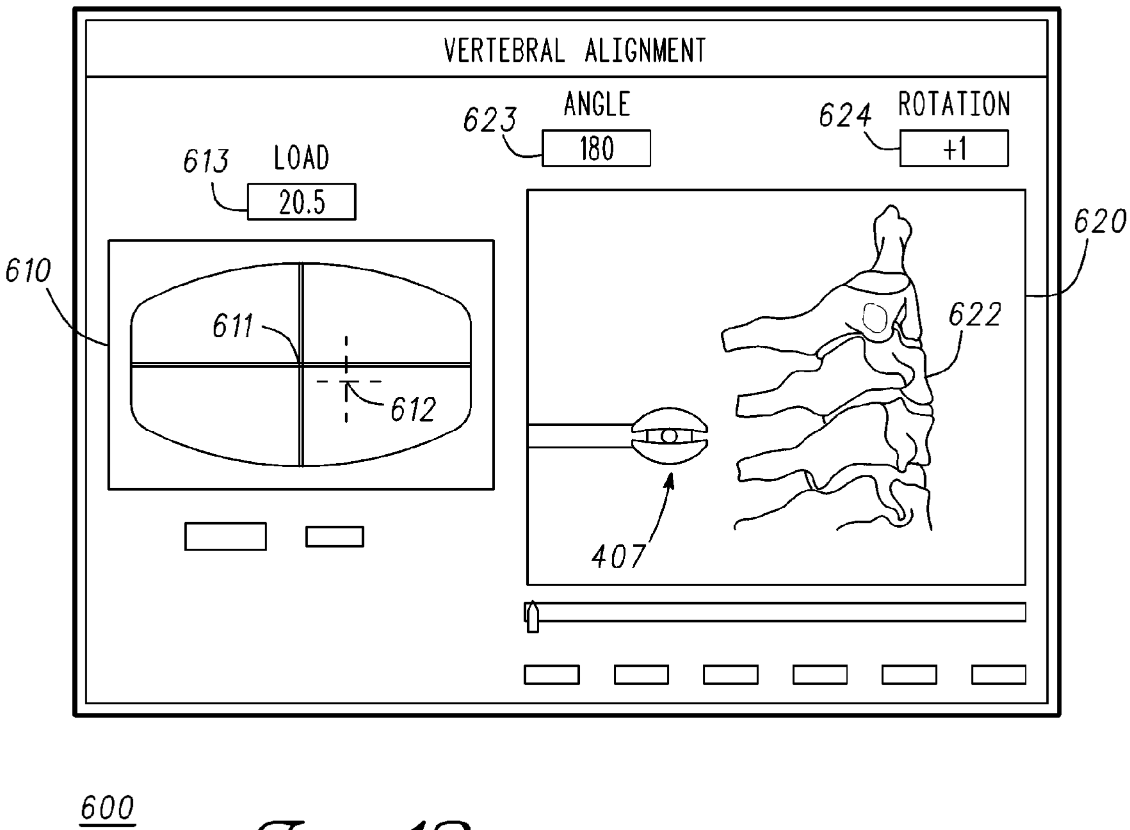

VERTEBRAL ALIGNMENT
ANGLE
ROTATION
623
180
624
+1
613
LOAD
20.5
620
610
611
612
622
407
600

Fig. 13

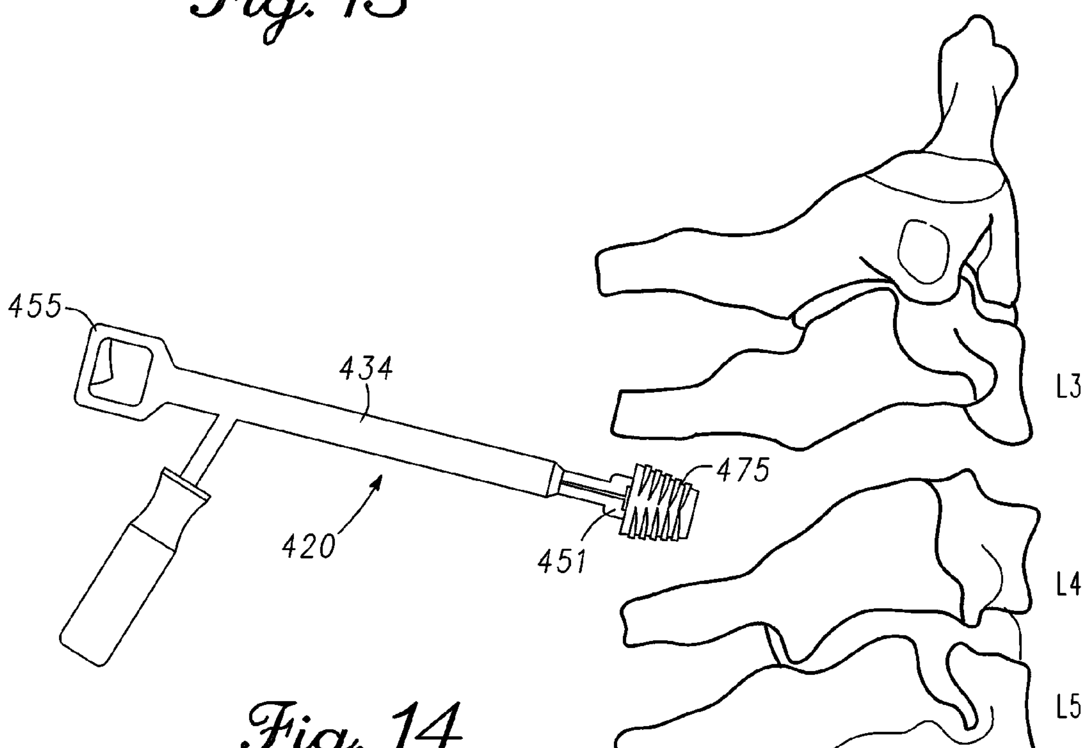

455
434
475
420
451
L3
L4
L5

Fig. 14

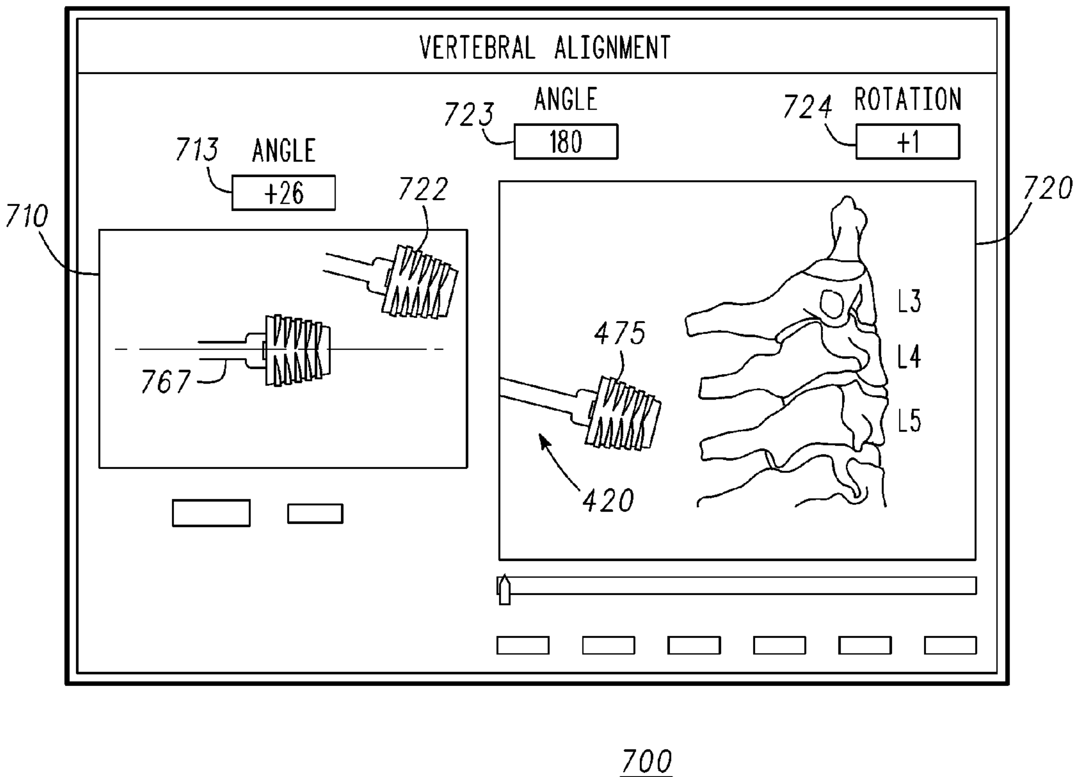

VERTEBRAL ALIGNMENT
723
ANGLE
180
724
ROTATION
+1
713
ANGLE
+26
722
710
720
L3
L4
L5
475
767
420
700

Fig. 15

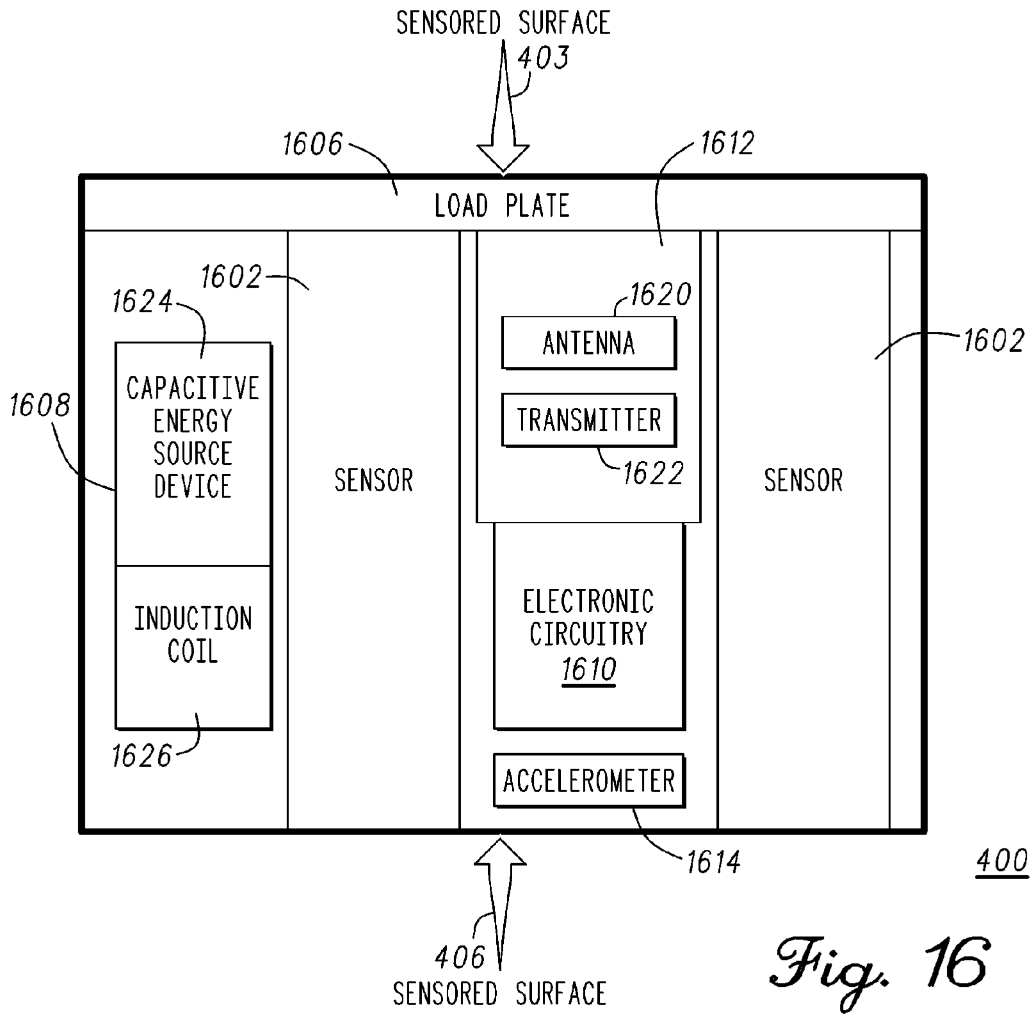

SENSORED SURFACE
403
1606
1612
LOAD PLATE
1602
1624
1620
ANTENNA
1602
1608
CAPACITIVE ENERGY SOURCE DEVICE
TRANSMITTER
SENSOR
1622
SENSOR
ELECTRONIC CIRCUITRY 1610
INDUCTION COIL
1626
ACCELEROMETER
1614
400
406
SENSORED SURFACE

Fig. 16

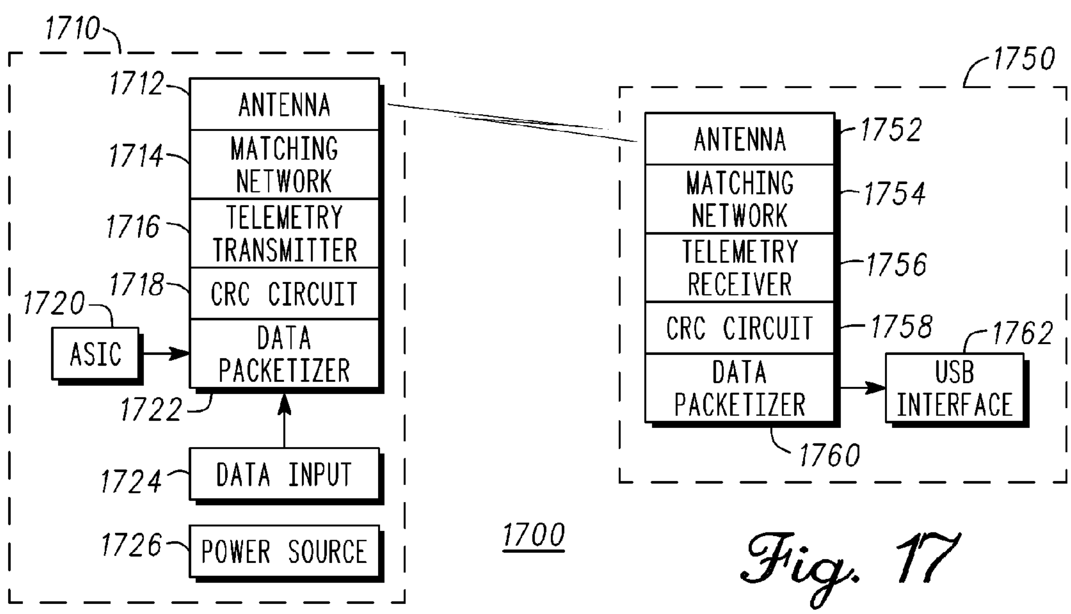
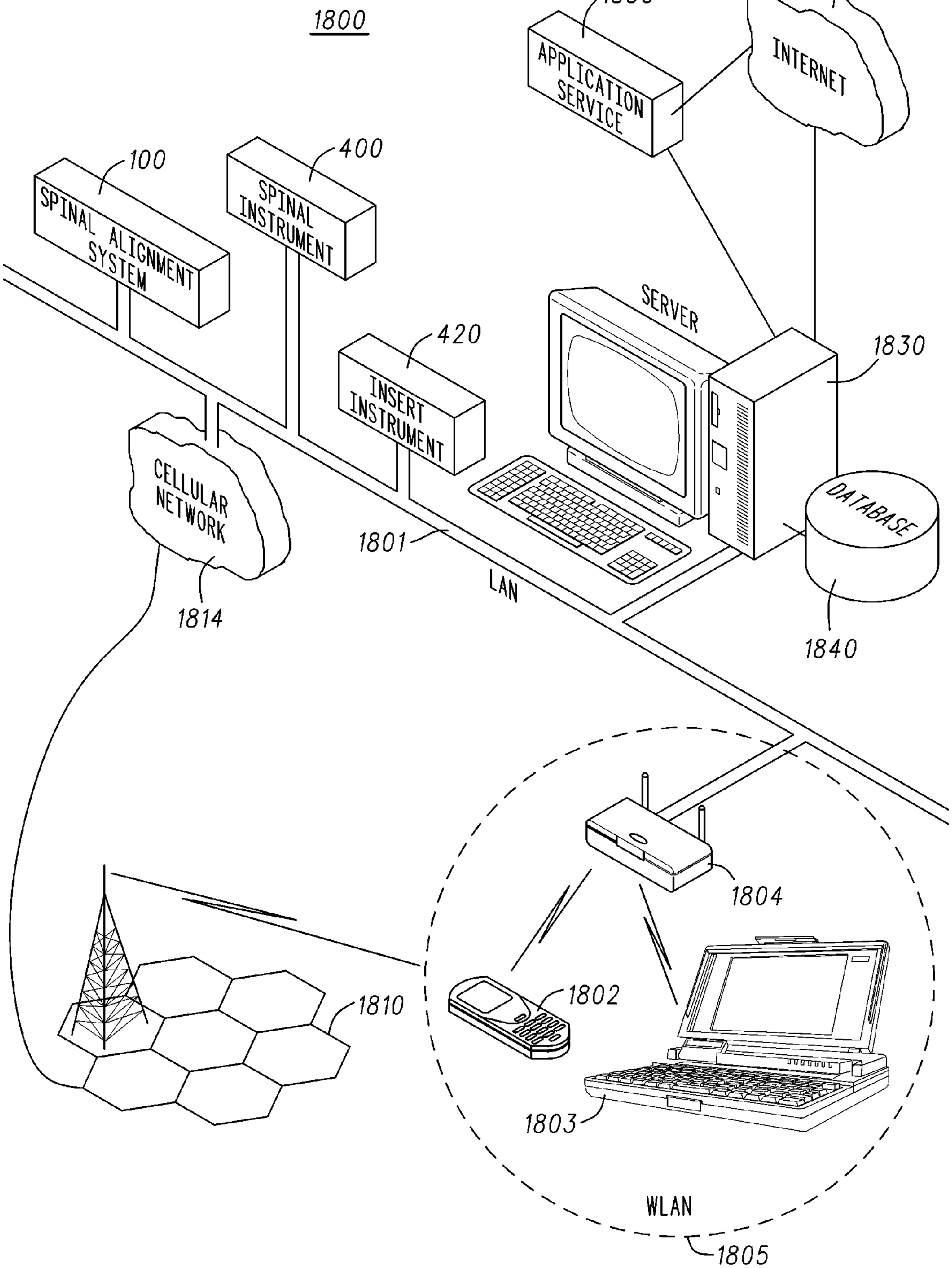

1710
1750
1712
ANTENNA
ANTENNA
1752
1714
MATCHING NETWORK
MATCHING NETWORK
1754
1716
TELEMETRY TRANSMITTER
TELEMETRY RECEIVER
1756
1718
CRC CIRCUIT
CRC CIRCUIT
1758
1720
ASIC
DATA PACKETIZER
DATA PACKETIZER
1762
USB INTERFACE
1722
1760
1724
DATA INPUT
1726
POWER SOURCE
1700

Fig. 17

Fig. 18


1800
1850
APPLICATION SERVICE
1820
INTERNET
100
SPINAL ALIGNMENT SYSTEM
400
SPINAL INSTRUMENT
420
INSERT INSTRUMENT
SERVER
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1810
1803
WLAN
1805

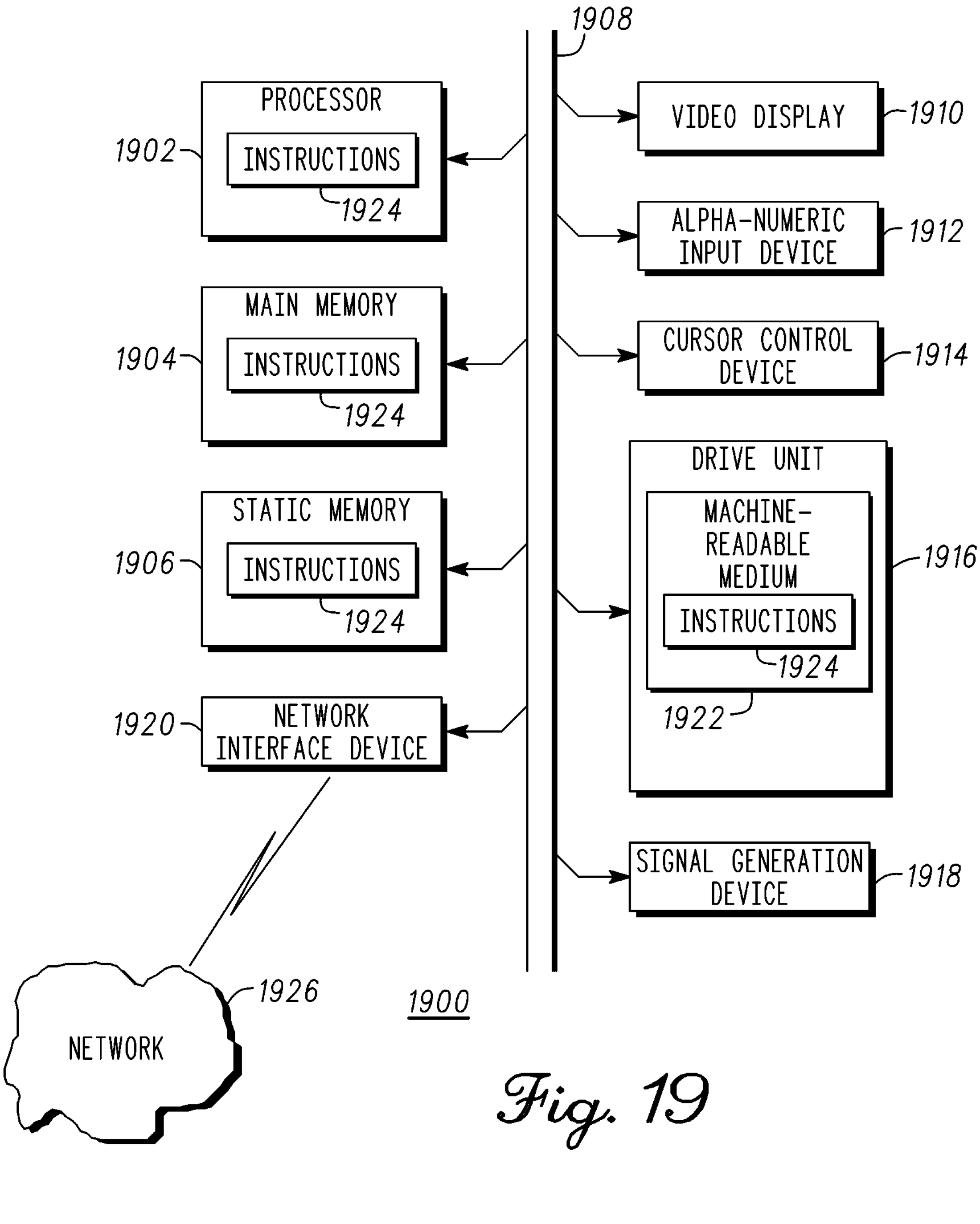
1908
PROCESSOR
INSTRUCTIONS
1902
1924
MAIN MEMORY
INSTRUCTIONS
1904
1924
STATIC MEMORY
INSTRUCTIONS
1906
1924
NETWORK INTERFACE DEVICE
1920
VIDEO DISPLAY
1910
ALPHA-NUMERIC INPUT DEVICE
1912
CURSOR CONTROL DEVICE
1914
DRIVE UNIT
MACHINE-READABLE MEDIUM
INSTRUCTIONS
1924
1922
1916
SIGNAL GENERATION DEVICE
1918
NETWORK
1926
1900

Fig. 19

SPINAL DISTRACTION TOOL FOR LOAD AND POSITION MEASUREMENT

FIELD

The present invention pertains generally to surgical electronics, and particularly to methods and devices for assessing alignment and surgical implant parameters during spine surgery and long-term implantation.

BACKGROUND

The spine is made up of many individual bones called vertebrae, joined together by muscles and ligaments. Soft intervertebral discs separate and cushion each vertebra from the next. Because the vertebrae are separate, the spine is flexible and able to bend. Together the vertebrae, discs, muscles, and ligaments make up the vertebral column or spine. The spine varies in size and shape, with changes that can occur due to environmental factors, health, and aging. The healthy spine has front-to-back curves, but deformities from normal cervical lordosis, thoracic kyphosis, and lumbar lordosis conditions can cause pain, discomfort, and difficulty with movement. These conditions can be exacerbated by herniated discs, which can pinch nerves.

There are many different causes of abnormal spinal curves and various treatment options from therapy to surgery. The goal of the surgery is a usually a solid fusion of the curved part of the spine. A fusion is achieved by operating on the spine, adding bone graft, and allowing the vertebral bones and bone graft to slowly heal together to form a solid mass of bone. Alternatively, a spinal cage is commonly used that includes bone graft for spacing and fusing vertebrae together. The bone graft may come from a bone bank or the patient's own hipbone. The spine can be substantially straightened with metal rods and hooks, wires or screws via instrumented tools and techniques. The rods or sometimes a brace or cast hold the spine in place until the fusion has a chance to heal.

BRIEF DESCRIPTION OF THE DRAWINGS

Various features of the system are set forth with particularity in the appended claims. The embodiments herein, can be understood by reference to the following description, taken in conjunction with the accompanying drawings, in which:

FIG. **1** illustrates a spinal alignment system in accordance with an example embodiment;

FIG. **2** illustrates a user interface showing spinal alignment and view projections in accordance with an example embodiment;

FIG. **3** illustrates the wand and the receiver of the spinal alignment system in accordance with an example embodiment;

FIG. **4** illustrates multiple sensorized devices for determining spinal alignment in accordance with an example embodiment;

FIG. **5** illustrates sensorized placement for determining spinal parameters in accordance with an example embodiment;

FIG. **6** illustrates placement of multiple sensors for determining spinal conditions in accordance with an example embodiment;

FIG. **7** illustrates a sensorized spinal instrument in accordance with an example embodiment;

FIG. **8** illustrates an integrated sensorized spinal instrument in accordance with an example embodiment;

FIG. **9** illustrates an insert instrument with vertebral components in a non-limiting example;

FIG. **10** illustrates the spinal instrument positioned between vertebra of the spine for parameter sensing in accordance with an example embodiment;

FIG. **11** illustrates a user interface showing a perspective view of the sensorized spinal instrument of FIG. **10** in accordance with an example embodiment;

FIG. **12** illustrates the sensorized spinal instrument positioned between vertebra of the spine for intervertebral position and force sensing in accordance with an example embodiment;

FIG. **13** illustrates a perspective view of a user interface showing the sensorized spinal instrument of FIG. **12** in accordance with an example embodiment;

FIG. **14** illustrates the sensorized spinal insert instrument for placement of a spine cage in accordance with an example embodiment;

FIG. **15** illustrates a perspective view of a user interface showing the sensorized spinal insert instrument of FIG. **14** in accordance with an example embodiment;

FIG. **16** is a block diagram of the components of the spinal instrument in accordance with an example embodiment;

FIG. **17** is a diagram of an exemplary communications system for short-range telemetry in accordance with an example embodiment;

FIG. **18** illustrates a communication network for measurement and reporting in accordance with an example embodiment; and

FIG. **19** depicts an exemplary diagrammatic representation of a machine in the form of a computer system within which a set of instructions, when executed, may cause the machine to perform any one or more of the methodologies disclosed herein.

DETAILED DESCRIPTION

While the specification concludes with claims defining the features of the embodiments of the invention that are regarded as novel, it is believed that the method, system, and other embodiments will be better understood from a consideration of the following description in conjunction with the drawing figures, in which like reference numerals are carried forward.

As required, detailed embodiments of the present method and system are disclosed herein. However, it is to be understood that the disclosed embodiments are merely exemplary, which can be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the embodiments of the present invention in virtually any appropriately detailed structure. Further, the terms and phrases used herein are not intended to be limiting but rather to provide an understandable description of the embodiment herein.

Broadly stated, embodiments of the invention are directed to a system and method for vertebral load and location sensing. A spine measurement system comprises a receiver and a plurality of wands coupled to a remote display that visually presents positional information. The wands can be placed on vertebra, or thereto touched, to report various aspects of spinal alignment. The positional information identifies an orientation and location of a wand and corresponding vertebrae of the spine. The system provides overall alignment plus the ability to track vertebral movement during a surgical operation. The system can propose and present intra-operative spine corrections in response to positional information captured during the procedure and previously recorded positional data related to a pre-operative spine condition.

The spine measurement system further includes a load balance and alignment system to assess load forces on the vertebra in conjunction with overall spinal alignment. The system includes a spine instrument having an electronic assembly and a sensorized head assembly that can articulate within a vertebral space. The sensorized head can be inserted between vertebra and report vertebral conditions such as force, pressure, orientation and edge loading. A GUI is used in conjunction therewith to show where the spine instrument is positioned relative to vertebral bodies as the instrument is placed in the inter-vertebral space during the surgical procedure. The system can report optimal prosthetic size and placement in view of the sensed load and location parameters including optional orientation, rotation and insertion angle along a determined insert trajectory.

An insert instrument is also provided herein with the load balance and alignment system for inserting a vertebral component such as a spine cage or pedicle screw. The system in view of previously captured parameter measurements can check and report if the instrument is edge loading during an insertion. It shows tracking of the insert instrument with the vertebral component and provides visual guidance and feedback based on positional and load sensing parameters. The system shows three-dimensional (3D) tracking of the insert instrument in relation to one or more vertebral bodies whose orientation and position are also modeled in 3D.

FIG. **1** illustrates a spinal alignment system **100** in a non-limiting example. The system **100** comprises a wand **103** and a receiver **101** that can be communicatively coupled to a remote system **105**. In general, one or more wands communicate with the receiver **101** to determine positional information that includes one of an orientation, rotation, angle, and location of a spinal region. The receiver **101** transmits positional information or data **117** regarding the wand **103** to the remote system **105**. The positional information includes orientation and translation data used to assess an alignment (or predetermined curvature) of the spine **112**. The remote system **105** can be a laptop or mobile workstation that presents a Graphical User Interface (GUI) **107**. The GUI **107** contains a workflow that shows the spine **112** and reports spinal alignment in view of positional information. As one example, the user interface can show an existing alignment **114** of the spinal vertebrae with respect to a post-surgical target alignment **113**.

The alignment system **100** can be communicatively coupled to a database **123** system such as a server **125** to provide three-dimensional (3D) imaging (e.g., soft tissue) and 3D models (e.g., bone) captured prior to, or during, surgery. The 3D imaging and models can be used in conjunction with the positional information to establish relative location and orientation. The server **125** may be local in near vicinity or remotely accessed over the internet **121**. As one example, the server **125** provides 3D spine and vertebra models. A CAT scanner (not shown) can be employed to produce a series of cross-sectional x-ray images of a selected part of the body. A computer operates the scanner, and the resulting picture represents a slice of the body. The server **125** produces a three-dimensional (3D) model from the slices. The server **125** can also provide 3D models generated from Magnetic Resonance Imaging (MRI) scanners (not shown). The server **125** may also support fluoroscopic imaging to provide real-time moving images of the internal structures of a patient with respect to the alignment system **100** devices through the use of X-ray source (not shown) and fluorescent screen.

The spine alignment system **100** reports overall alignment and instrument (e.g., wand **103** and receiver **101**) orientation plus the ability to track isolated vertebral movement. The receiver **101** precisely tracks the location of the wand **103** at a particular vertebra and along the spine **112** to determine the positional information. The receiver **101** is shown coupled (e.g., pinned, screwed, affixed) to the sacrum. However, it can be located anywhere along the vertebrae of the spine. Alternatively, it can be mounted to a stand in the vicinity of the spine **112**. The wand **103** and receiver **101** are sensorized devices that can transmit their position via ultrasonic, optical, or electromagnetic sensing. In the example, the wand **103** and the receiver **102** utilize ultrasonic transducers and are line of sight devices. The sensors may be externally mounted on the wand **103** away from the wand tip, or in some cases, within the wand tip. The wand **103** can be held in the hand or affixed to the spine via a mechanical assembly. In one embodiment, the components for generating all alignment measurements (e.g. receiver **101** and wand **103**) reside within a sterile field **109** of an operating room. The sterile field **109** can also be called a surgical field. Typically, the remote system **105** is outside the sterile field **109** of the operating room. The components used within the sterile filed **109** can be designed for a single use. In the example, the wand **103**, receiver **102**, or both are disposed of after being used intra-operatively.

One example of an ultrasonic sensing device is disclosed in U.S. patent application Ser. No. 11/683,410 entitled "Method and Device for Three-Dimensional Sensing" filed Mar. 7, 2007 the entire contents of which are hereby incorporated by reference. One example of optical sensing includes three or four active IR reflectors on the wand **103** with corresponding high-speed camera elements on the receiver **101** for optical tracking, or alternatively high-speed photo-diode elements for detecting incident light beam angles and thereafter triangulating a wand position. One example of electromagnetic sensing includes metallic spheres on the wand whose spatial location is determined by evaluating changes in generated magnetic field strengths on the receiver **103**.

Many physical parameters of interest within physical systems or bodies can be measured by evaluating changes in the characteristics of energy waves or pulses. As one example, changes in the transit time or shape of an energy wave or pulse propagating through a changing medium can be measured to determine the forces acting on the medium and causing the changes. The propagation velocity of the energy waves or pulses in the medium is affected by physical changes in of the medium. The physical parameter or parameters of interest can include, but are not limited to, measurement of load, force, pressure, displacement, density, viscosity, and localized temperature. These parameters can be evaluated by measuring changes in the propagation time of energy pulses or waves relative to orientation, alignment, direction, or position as well as movement, rotation, or acceleration along an axis or combination of axes by wireless sensing modules or devices positioned on or within a body, instrument, equipment, or other mechanical system. Alternatively, measurements of interest can be taken using film sensors, mechanical sensors, polymer sensors, mems devices, strain gauge, piezo-resistive structure, and capacitive structures to name but a few.

FIG. **2** illustrates a graphical user interface (GUI) **150** of the system **100** showing spinal alignment and view projections in a non-limiting example. The view projections provide three-dimensional visualization to the surgical procedure and system devices of FIG. **1** while displaying the quantitative measurements in real-time. Each view projection can be separately configured to show a different perspective of the spine with superimposed spine alignment information. The first view projection **210** shows a sagital view (i.e., front to back). The second view projection **230** shows a coronal view (i.e., side to side). The sagital and coronal views provide sufficient spatial information to visualize spine alignment with only two viewing projections. The view projections can be customized for different view angles and scene graphs.

As one example, the surgeon can hold the wand **103** and trace a contour of the spine, for instance, to determine the severity (or correction) of a scoliosis condition. This may be done prior to a surgery while the patient is standing to provide an indication of the patient's posture and spine curvature. The surgeon holds the wand and follows the contour of the spine. The GUI **108** visually shows the spinal contour from the positional information captured from the wand **103** during the trace. An alignment angle is then calculated from first order statistics and geometry (e.g., see angle points R, P**1** and P**2**, where R is reference alignment, P**1** is location of receiver **101**, and P**2** is point registered by wand **103**). The alignment angle indicates the offset of the spinal alignment, and when projected in the view planes, shows the deviation error in the sagital and coronal planes. The GUI **108** can then report the required compensatory correction. In the current example, for instance, it reports a +4 cm forward required displacement in display box **146** to correct for sagital deviation of the angle between line **152** and line **154**, and a +2 cm right required displacement in display box **148** to correct for coronal deviation of the angle between line **158** and line **156**. This provides the surgeon with the minimal visual information to provide surgical alignment corrections.

Alternatively, a fast point-registration method can be employed to assess spinal alignment. The point registration method permits the surgeon to quickly assess spinal alignment with minimal registration. The user holds the wand and points and clicks on vertebra to create a point curve, which is converted to a line. In a first step A, the receiver **101** is positioned at a stationary location, for example, on a stand near the operating table. Alternatively, the receiver **101** can be rigidly pinned to the sacrum as shown in FIG. **1**. In a second step B, the surgeon identifies three or more anatomical features on a reference bone with the wand **103** tip, such as points along the posterior iliac crest or dorsal surface on the sacrum. The system **100** determines the reference bone orientation from the registered wand tip spatial locations, for example, in a <x,y,z> Cartesian coordinate system relative to the receiver **101** origin. The system **100** then retrieves the associated 3D model spine components (e.g., sacrum, vertebra, etc.) from the image server **125**, and displays them on the GUI **108** with the proper scaling and orientation (morphing and warping) in accordance with the reference bone orientation. Once the 3D model registration is complete, and while the patient remains stationary, the surgeon then registers one of the vertebrae, for example cervical vertebrae (C1-C7), in a third step C. The system **100** then has sufficient registered points to create a local coordinate system relative to the reference bone, generate a curve and line segment and report overall alignment as shown in FIG. **2**. The spinal alignment is reported in view of a predetermined curvature or a straightness of the spine, for example, showing line **152** versus desired (pre-op planning) line **154**.

FIG. **3** illustrates a non-limiting example of the wand **103** and the receiver **101**, though, not all the components shown are required; fewer components can be used depending on required functionality. The receiver **101** and wand **103** and communication modes of operations there between are disclosed in U.S. patent application Ser. No. 12/900,662 entitled "Navigation Device Providing Sensory Feedback" filed Oct. 8, 2010; the entire contents of which are hereby incorporated by reference. Briefly, the current dimensions permit touchless tracking with sub millimeter spatial accuracy (<1 mm) up to approximately 2 m in distance. Either device and can be configured to support various functions (e.g., hand-held, mounted to object) and neither is limited to the dimensions described below.

The wand **103** is a hand-held device with a size dimension of approximately 10 cm in width, 2 cm depth, and an extendable length from 18 cm to 20 cm. As indicated above, the wand **103** can register points of interest (see points A, B, C), for example, along a contour of an object or surface, which can be shown in a user interface (see GUI **107** FIG. **1**). As will be discussed ahead, the wand **103** and receiver **101** can communicate via ultrasonic, infrared and electromagnetic sensing to determine their relative location and orientation to one another. Other embodiments incorporating accelerometers provide further positional information.

The wand **103** includes sensors **201**-**203** and a wand tip **207**. The sensors can be ultrasonic transducers, Micro Electro Mechanical Element (MEMS) microphones, electromagnets, optical elements (e.g., infrared, laser), metallic objects or other transducers for converting or conveying a physical movement to an electric signal such as a voltage or current. They may be active elements in that they are self-powered to transmit signals, or passive elements in that they are reflective or exhibit detectable magnetic properties.

In one embodiment, the wand **103** comprises three ultrasonic transmitters **201**-**203** each transmitting ultrasonic signals through the air, a controller (or electronic circuit) **214** for generating driver signals to the three ultrasonic transmitters **201**-**203** for generating the ultrasonic signals, an user interface **218** (e.g., button) that receives user input for performing short range positional measurement and alignment determination, a communications module **216** for relaying the user input and receiving timing information to control the electronic circuit **214**, and a battery **218** for powering the electronic circuit **218** and associated electronics on the wand **103**. The controller **214** is operatively coupled to the ultrasonic transmitters **201**-**203**. Transmitters **201**-**203** transmit sensory signals in response to a directive by the controller **214**. The wand **103** may contain more or less than the number of components shown; certain component functionalities may be shared as integrated devices.

Additional transmitter sensors can be included to provide an over-determined system for three-dimensional sensing. As one example, each ultrasonic transducer can perform separate transmit and receive functions. One such example of an ultrasonic sensor is disclosed in U.S. Pat. No. 7,725,288 the entire contents of which are hereby incorporated by reference. The ultrasonic sensors can transmit pulse shaped waveforms in accordance with physical characteristics of a customized transducer for constructing and shaping waveforms.

The wand tip **207** identifies points of interest on a structure, for example, an assembly, object, instrument or jig in three-dimensional space but is not limited to these. The tip does not require sensors since its spatial location in three-dimensional space is established by the three ultrasonic transmitters **201**-**203** arranged at the cross ends. However, a tip sensor **219** can be integrated on the tip **207** to provide ultrasound capabilities (e.g., structure boundaries, depth, etc.) or contact based sensing. In such case, the tip **207** can be touch sensitive to register points responsive to a physical action, for example, touching the tip to an anatomical or structural location. The tip can comprise a mechanical or actuated spring assembly for such purpose. In another arrangement it includes a capacitive touch tip or electrostatic assembly for registering touch. The wand tip **207** can include interchangeable, detachable or multi-headed stylus tips for permitting the wand tip to identify anatomical features while the transmitters **201**-**203** remain in line-of-sight with the receiver **101** (see FIG. **1**). These stylus tips may be right angled, curved, or otherwise contoured in fashion of a pick to point to difficult to touch locations. This permits the wand to be held in the hand to identify via the tip **207**, points of interest such as (anatomical) features on the structure, bone or jig.

The user interface **218** can include one or more buttons to permit handheld operation and use (e.g., on/off/reset button) and illumination elements to provide visual feedback. In one arrangement, an 8-state navigation press button **209** can communicate directives to further control or complement the user interface. It can be ergonomically located on a side of the wand to permit single-handed use. The wand **103** may further include a haptic module with the user interface **218**. As an example, the haptic module may change (increase/decrease) vibration to signal improper or proper operation. The wand **103** includes material coverings for the transmitters **201**-**202** that are transparent to sound (e.g., ultrasound) and light (e.g., infrared) yet impervious to biological material such as water, blood or tissue. In one arrangement, a clear plastic membrane (or mesh) is stretched taught; it can vibrate under resonance with a transmitted frequency. The battery **218** can be charged via wireless energy charging (e.g., magnetic induction coils and super capacitors).

The wand **103** can include a base attachment mechanism **205** for coupling to a structure, object or a jig. As one example, the mechanism can be a magnetic assembly with a fixed insert (e.g., square post head) to permit temporary detachment. As another example, it can be a magnetic ball and joint socket with latched increments. As yet another example, it can be a screw post or pin to an orthopedic screw. Other embodiments may permit sliding, translation, rotation, angling and lock-in attachment and release, and coupling to standard jigs by way of existing notches, ridges or holes.

The wand **103** can further include an amplifier **213** and an accelerometer **217**. The amplifier enhances the signal to noise ratio of transmitted or received signals. Accelerometer **217** identifies 3 and 6 axis tilt during motion and while stationary. Communications module **216** may include components (e.g., synchronous clocks, radio frequency 'RF' pulses, infrared 'IR' pulses, optical/acoustic pulse) for signaling to the receiver **101**. The controller **214**, can include a counter, a clock, or other analog or digital logic for controlling transmit and receive synchronization and sequencing of the sensor signals, accelerometer information, and other component data or status. The battery **218** powers the respective circuit logic and components. Infrared transmitter **209** pulses an infrared timing signal that can be synchronized with the transmitting of the ultrasonic signals (to the receiver).

Controller **214** can utilize computing technologies such as a microprocessor (uP) and/or digital signal processor (DSP) with associated storage memory **208** such as Flash, ROM, RAM, SRAM, DRAM or other like technologies for controlling operations of the aforementioned components of the device. The instructions may also reside, completely or at least partially, within other memory, and/or a processor during execution thereof by another processor or computer system. An Input/Output port permits portable exchange of information or data for example by way of Universal Serial Bus (USB). The electronic circuitry of the controller **214** can comprise one or more Application Specific Integrated Circuit (ASIC) chips or Field Programmable Gate Arrays (FPGAs), for example, specific to a core signal-processing algorithm. The controller **214** can be an embedded platform running one or more modules of an operating system (OS). In one arrangement, the storage memory may store one or more sets of instructions (e.g., software) embodying any one or more of the methodologies or functions described herein.

The receiver **101** comprises a processor **233** for generating timing information, registering a pointing location of the wand **103** responsive to the user input, and determining short range positional measurement and alignment from three or more pointing locations of the wand **103** with respect to the receiver **101**. The receiver has size dimensions of approximately 2 cm width, 2 cm depth, and a length of 10 cm to 20 cm. It includes a communications module **235** for transmitting the timing information to the wand **103** that in response transmits the first, second and third ultrasonic signals. The ultrasonic signals can be pulse shaped signals generated from a combination of amplitude modulation, frequency modulation, and phase modulation. Three microphones **221**-**223** each receive the first, second and third pulse shaped signals transmitted through the air. Receiver **101** can be configured lineal or in more compact arrangements, it can comprise a triangular shape. One example of a device for three-dimensional sensing is disclosed in U.S. patent application Ser. No. 11/683,410 entitled "Method and Device for Three-Dimensional Sensing" filed Mar. 7, 2007 the entire contents of which are hereby incorporated by reference.

The memory **238** stores the ultrasonic signals and can produce a history of ultrasonic signals or processed signals. It can also store wand tip positions, for example, responsive to a user pressing the button to register a location. The wireless communication interface (Input/Output) **239** wirelessly conveys the positional information and the short-range alignment of the three or more pointing locations to a remote system. The remote system can be a computer, laptop or mobile device that displays the positional information and alignment information in real-time as described ahead. The battery powers the processor **233** and associated electronics on the receiver **101**. The receiver **101** may contain more or less than the number of components shown; certain component functionalities may be shared or therein integrated.

Additional ultrasonic sensors can be included to provide an over-determined system for three-dimensional sensing. The ultrasonic sensors can be MEMS microphones, receivers, ultrasonic transmitters or combination thereof. As one example, each ultrasonic transducer can perform separate transmit and receive functions. One such example of an ultrasonic sensor is disclosed in U.S. Pat. No. 7,414,705 the entire contents of which are hereby incorporated by reference. The receiver **101** can also include an attachment mechanism **240** for coupling to bone or a jig by way of the pin **251**. As one example, attachment mechanism **240** can be a magnetic assembly with a fixed insert (e.g., square post head) to permit temporary detachment. As another example, it can be a magnetic ball and joint socket with latched increments.

The receiver **101** can further include an amplifier **232**, communications module **235**, an accelerometer **236**, and processor **233**. The processor **233** can host software program modules such as a pulse shaper, a phase detector, a signal compressor, and other digital signal processor code utilities and packages. The amplifier **232** enhances the signal to noise of transmitted or received signals. The processor **233** can include a controller, counter, a clock, and other analog or digital logic for controlling transmit and receive synchronization and sequencing of the sensor signals, accelerometer information, and other component data or status. The accelerometer **236** can identify axial tilt (e.g., 3 and 6 axis) during motion and while stationary. The battery **234** powers the respective circuit logic and components. The receiver includes a photo diode **241** for detecting the infrared signal and establishing a transmit time of the ultrasonic signals to permit wireless infrared communication with the wand.

The communications module **235** can include components (e.g., synchronous clocks, radio frequency 'RF' pulses, infrared 'IR' pulses, optical/acoustic pulse) for local signaling (to wand **102**). It can also include network and data components (e.g., Bluetooth, ZigBee, Wi-Fi, GPSK, FSK, USB, RS232, IR, etc.) for wireless communications with a remote device (e.g., laptop, computer, etc.). Although external communication via the network and data components is herein contemplated, it should be noted that the receiver **101** can include a user interface **237** to permit standalone operation. As one example, it can include 3 LED lights **224** to show three or more wand tip pointing location alignment status. The user interface **237** may also include a touch screen or other interface display with its own GUI for reporting positional information and alignment.

The processor **233** can utilize computing technologies such as a microprocessor (uP) and/or digital signal processor (DSP) with associated storage memory **238** such a Flash, ROM, RAM, SRAM, DRAM or other like technologies for controlling operations of the aforementioned components of the terminal device. The instructions may also reside, completely or at least partially, within other memory, and/or a processor during execution thereof by another processor or computer system. An Input/Output port permits portable exchange of information or data for example by way of Universal Serial Bus (USB). The electronic circuitry of the controller can comprise one or more Application Specific Integrated Circuit (ASIC) chips or Field Programmable Gate Arrays (FPGAs), for example, specific to a core signal processing algorithm or control logic. The processor can be an embedded platform running one or more modules of an operating system (OS). In one arrangement, the storage memory **238** may store one or more sets of instructions (e.g., software) embodying any one or more of the methodologies or functions described herein.

In a first arrangement, the receiver **101** is wired via a tethered electrical connection (e.g., wire) to the wand **103**. That is, the communications port of the wand **103** is physically wired to the communications interface of the receiver **101** for receiving timing information. The timing information from the receiver **101** tells the wand **103** when to transmit and includes optional parameters that can be applied to pulse shaping. The processor **233** on the receiver **101** employs this timing information to establish Time of Flight measurements in the case of ultrasonic signaling with respect to a reference time base.

In a second arrangement, the receiver **101** is communicatively coupled to the wand **103** via a wireless signaling connection via wireless I/O **239**. A signaling protocol is disclosed in U.S. patent application Ser. No. 12/900,662 entitled "Navigation Device Providing Sensory Feedback" filed Oct. 8, 2010; the entire contents of which are hereby incorporated by reference. An infrared transmitter **209** on the wand **103** transmits an infrared timing signal with each transmitted pulse shaped signal. It pulses an infrared timing signal that is synchronized with the transmitting of the ultrasonic signals to the receiver. The receiver **101** can include a photo diode **241** for determining when the infrared timing signal is received. In this case, the communications port of the wand **103** is wirelessly coupled to the communications interface of the receiver **101** by way of the infrared transmitter and the photo diode for relaying the timing information to within microsecond accuracy (~1 mm resolution). The processor **233** on the receiver **101** employs this infrared timing information to establish the first, second, and third Time of Flight measurements with respect to a reference transmit time.

FIG. **4** illustrates multiple sensorized wands for evaluating spinal alignment **300** in a non-limiting example. As shown, multiple sensorized wands **301-304** can be employed to track individual vertebral movement and/or alignment relative to other tracked vertebrae. Each of the wands may be of a different size and sensor configuration. The wands are lightweight components that can span dimensions between 4 cm to 12 cm, and width of less than or equal to 1 cm. In general, the wands **301-304** have a form factor easily held by hand or can be attached and supported by the muscular-skeletal system. For example, a first wand **301** may have a wider and longer sensor span than another wand **303**. This can enhance communication between the wands **301-304** and receiver **308**. Each wand can have a separate ID to identify it from the others, for example, stored as a characteristic low frequency magnetic wavelength unique to the wand. The system **100** can identify the wands via the passive magnetic field and determine position via the one or more ultrasonic, optical, electromagnetic elements, or (passive/active) sensors.

In conjunction with the illustration of FIG. **4**, a workflow method is herein contemplated. At a first workflow step **311**, the receiver **308** is positioned in proximity to the surgical area and where the wands are expected to be used. As previously noted, the receiver **308** is placed on a stand or affixed to the sacrum (or other bony region) to track a wand's orientation and location. A wand may be held in a hand and used to register anatomic features on sacrum, for example, point and click the wand tip to a bone feature. This point registration captures anatomical points, which are then used to retrieve a 3D spine model with proper orientation and dimension. At step **312**, the wand can then be used to register points on a vertebra to assess a location of that vertebra. In a first arrangement, the wand can be affixed to the vertebra directly without any wand tip point registration. This provides one point for assessing spatial location at the insertion point but not necessarily orientation (three-dimensional information).

In a second arrangement, the wand is first used to register points on the surface of the vertebra and then inserted therein. The registration captures anatomical vertebra points, which are then used to retrieve a 3D vertebra model with proper orientation and dimension. This permits the system **100** to track the vertebra with proper scaling and position when the wand is inserted therein. During the registration and positioning of the receiver on the sacrum and each wand on the vertebrae, the system **100** provides a real-time view of the instrument tracking as shown in step **313**. That is, it produces a virtual environment showing the 3D model of the spine, sensorized wands **301-304** and receiver **308**.

FIG. **5** illustrates sensorized placement for determining spinal conditions in a non-limiting example. As previously noted, the wand-tip may also include a sensor, such as a biometric transducer. The wand tip when used to register a point of interest can also capture biometric data directly related to the insertion site. The wand tip can also disengage the biometric transducer and leave it positioned at the site of contact. The illustrations of FIGS. **5** and **6** illustrate the placement of the wand tip sensor, which in some configurations deploys its tip sensor in-situ for long term implantation. The system **100** can also enable a transfer of energy waves in a vibratory pattern that can mimic load on the bone and lead to improved bone mineral content and density. The sensors can also send energy waves through or across an implant to, thus, aid in healing of a fracture.

Accordingly, a method is herein provided for detecting biometric parameters, which are a function of sensorized placement including position and orientation. The method includes providing a biometric transducer on a moving component of a vertebral joint, transmitting an energy wave (e.g., ultrasonic, optical, electromagnetic) from the biometric transducer into a procedure area different from the moving component of the vertebral joint during vertebral joint or spine motion, quantatively assessing the behavior of the energy wave during the vertebral joint motion; and based upon the assessed behavior and vertebral joint motion, determining a current status or at least one parameter of the procedure area selected from the group consisting of pressure, tension, shear, load, torque, bone density and bearing weight. Alternatively, an insertible head assembly incorporating one or more sensors can be used to measure the biometric parameter of interest. In the example, the biometric transducer can detect and transmit information regarding motion and loads of vertebra. As one example, the sensors can detects abnormal motion of the orthopedic joint by evaluating a frequency or periodicity of the assessed behavior, for example, as the vertebral joint is flexed during movement.

As one example shown in FIG. **5**, a single sensor **352** can be implanted on a bone or prosthetic component of the vertebral joint (e.g., vertebra) to assess behavior of the vertebral joint during movement, such as, a quality or functionality of the joint mechanics as related to pressure, tension, shear, bone density and bearing weight. The sensor **352** in this embodiment is at a fixed location on the bone (vertebra) and moves with the vertebra **358** during motion relative to the procedure area **360**. As shown, the procedure area **360** comprises vertebra **354**, disc **356**, and vertebra **358**. The procedure area **360** is relatively stationary with respect to the sensor since the vertebra primarily moves the single sensor. The single sensor in this arrangement is exposed to various changes in the parameter of interest (e.g., pressure, tension, shear, bone density, and bearing weight) in the procedure area as a result of the motion. As one example, the sensor is compressed through the range of joint movement consequent to actions applied at different locations in the joint during the motion. During motion, sensor **352** assesses the energy waves in the procedural area; an adjacent area is also assessed because the movement of the vertebra (and accordingly the sensor focus) changes with respect to the procedure area as a result of the motion. The position of sensor **352** (by way of the wand when attached thereto) is also determined in relation to the other vertebra and used to catalog changes in the sensed parameter with respect to orientation, location and position.

One advantage of placing sensor **352** on a moving component (e.g., vertebra, prosthetic implant) and transmitting an energy wave into a procedure area different from the moving component of the vertebral joint, with knowledge of its location and orientation, is that it effectively changes the distance between sensor **352** and the procedure area which changes the resolution and focus of sensor **352** as well as forces thereon. The positional information also indicates periodicity of movement as related to changes in the sensed parameter. As one example, sensor **352** operating in a switched transmit and receive mode can take measurements at different depths of the procedure area without incurring operational changes. Sensor **352** as a result of the changing distance due to joint movement, can take different measurements without sensor adjustment that could otherwise require changing a frequency, amplitude, or phase of the transmitted energy wave, for example, to match impedances.

As one example, biometric sensor **352** can be an ultrasound device. Quantitative ultrasound, in contrast to other bone-densitometry methods that measure only bone-mineral content, can measure additional properties of bone such as mechanical integrity. Propagation of the ultrasound wave through bone is affected by bone mass, bone architecture, and the directionality of loading. Quantitative ultrasound measurements as measures for assessing the strength and stiffness of bone are based on the processing of the received ultrasound signals. The speed of sound and the ultrasound wave propagates through the bone and the soft tissue. Prosthetic loosening or subsidence, and fracture of the femur/tibia/acetabulum or the prosthesis, are associated with bone loss. Consequently, an accurate assessment of progressive quantifiable changes in periprosthetic bone-mineral content may help the treating surgeon to determine when to intervene in order to preserve bone stock for revision arthroplasty. This information helps in the development of implants for osteoporotic bone, and aids in the evaluation of medical treatment of osteoporoses and the effects of different implant coatings.

FIG. **6** illustrates multiple sensorized placements for determining spinal conditions in a non-limiting example. As previously noted, the wand-tip may also include a sensor, such as a biometric transducer. The wand tip when used to register a point of interest can also capture biometric data directly related to the insertion site. The wand tip can also disengage the biometric transducer and leave it positioned at the site of contact.

Accordingly, a method is herein provided for detecting biometric parameters comprising providing a second biometric transducer at the procedure area that is different from the moving component of the vertebral joint, and quantatively assessing the behavior of the energy wave based on a relative separation of the first biometric transducer and second biometric transducer during the vertebral joint motion. A current status or at least one parameter of the procedure area is determined from the assessed behavior and vertebral joint motion. The parameter is one of strain, vibration, kinematics, and stability. A first biometric transducer or the second biometric transducer can include a transceiver for transmitting data relating to the at least one biometric parameter to an external source for assessment.

As shown in FIG. **6** sensor **352** can be implanted on a bone or prosthetic component of an vertebral joint (e.g., vertebra) and a sensor **366** can be positioned at a different position in the procedure area for assessing behavior of the vertebral joint during movement. Sensor **352** in this embodiment is at a fixed location on the bone (vertebra) and moves with the vertebra during joint motion relative to sensor **366** in the procedure area. The sensor **366** can be on a different bone. Although both sensors can move, sensor **352** in effect can be considered moving relative to sensor **366** and is relatively displaced as indicated. The sensors **352** and **366** allow evaluation of the host bone and tissue regarding, but not limited to bone density, fluid viscosity, temperature, strain, pressure, angular deformity, vibration, load, torque, distance, tilt, shape, elasticity, motion, and others.

The dual sensor arrangement shown can evaluate of bone integrity. For instance, in a vertebral joint, sensors **352** and **366** coupled to a first and second vertebra assess the bone density. External and internal energy waves sent by sensor **352**, sensor **366**, or both according to the invention can be used during the treatment of fractures and spinal fusions. With two deployed sensors, the distance between the sensors can be determined at the area of concern and the power field that can be generated. The energy fields can be standard energy sources such as ultrasound, radiofrequency, and/or electromagnetic fields. The deflection of the energy wave over time, for example, will allow the detection of changes in the desired parameter that is being evaluated. As an example, a first sensor placed on a distal end of the femur bone can assess bone density from a second sensor embedded on a proximal end of the tibia bone during vertebral movement.

One advantage of two or more sensors is that they move closer and farther apart relative to one another as a result of the motion; actions that improve an assessment of the energy wave, for example, due to the frequency characteristics of the sensors and impedance characteristics of the procedure area under investigation. Again, the relative separation of sensors **352** and **366** may permit taking different measurements without sensor adjustment that could otherwise require changing a frequency, amplitude, or phase of the transmitted energy wave, for example, to match impedances. In the current example, the measurement of bone is based on the processing of the received ultrasound signals. Speed of the sound and the ultrasound velocity both provide measurements on the basis of how rapidly the ultrasound wave propagates through the bone and the soft tissue. These measures characteristics permit creation of a rapid three-dimensional geometry, which information can be processed by the system **100** in conjunction with positional, orientation and location information. Because the sensors span a joint space, they can detect changes in the implant function. Examples of implant functions include bearing wear, subsidence, bone integration, normal and abnormal motion, heat, change in viscosity, particulate matter, kinematics, to name a few.

FIG. **7** illustrates a sensorized spinal instrument **400** in a non-limiting example. A side view and a top view are presented. Spinal instrument **400** comprises a handle **409**, a shaft **430**, and a sensored head **407**. The handle **409** is coupled at a proximal end of the shaft **430** and the sensored head **407** is coupled to a distal end of the shaft **430**. In one embodiment, handle **409**, shaft **430**, and sensored head **407** form a rigid structure that does not flex when used to distract or measure a spinal region. Spinal instrument **400** includes an electronic assembly **401** operatively coupled to one or more sensors in sensored head **407**. The sensors are coupled to surfaces **403**/**406** on moving components **404**/**405** of sensored head **407**. The electronic assembly **401** is located towards the proximal end of the shaft **407** or in handle **409**. As shown, the electronic assembly **401** is coupled to shaft **409**. Electronic assembly **401** comprises electronic circuitry that includes logic circuitry, an accelerometer, and communication circuitry. In one embodiment, surfaces **403** and **406** of sensored head **407** can have a convex shape. The convex shape of surfaces **403** and **406** support placement of sensored head **407** within the spinal region and more specifically between the contours of vertebrae. In one embodiment, sensored head **407** is height adjustable by way of the top component **404** and the bottom component **405** through a jack **402** that evenly distracts and closes according to handle **409** turning motion **411**. Jack **402** is coupled to interior surfaces of components **404** and **405** of sensored head **407**. Shaft **430** includes one or more lengthwise passages. For example, interconnect such as a flexible wire interconnect can couple through one lengthwise passage of shaft **430** such that electronic assembly **401** is operatively coupled to one or more sensors in sensored head **407**. Similarly, a threaded rod can couple through a second passage of shaft **430** for coupling handle **409** to jack **404** thereby allowing height adjustment of sensored head **407** via rotation of handle **409**.

Spine instrument **400** can also determine an orientation by way of embedded accelerometers. The sensored head **407** supports multiple functions that include the ability to determine a parameter of the procedure area (e.g., intervertebral space) including pressure, tension, shear, load, torque, bone density, and/or bearing weight. In one embodiment, more than one load sensor can be included within sensored head **407**. The more than one load sensors can be coupled to predetermined locations of surfaces **403** and **406**. Having more than one load sensor allows the sensored head **407** to measure load magnitude and the position of applied load to surfaces **403** and **406**. The sensored head **407** can be used to measure, adjust, and test a vertebral joint prior to installing a vertebral component. As will be seen ahead, the alignment system **100** evaluates the optimal insertion angle and position of the spine instrument **400** during intervertebral load sensing and replicates these conditions when using an insert instrument.

In the present invention these parameters can be measured with an integrated wireless sensored head **407** or device comprising an i) encapsulating structure that supports sensors and contacting surfaces and ii) an electronic assemblage that integrates a power supply, sensing elements, ultrasound resonator or resonators or transducer or transducers and ultrasound waveguide or waveguides, biasing spring or springs or other form of elastic members, an accelerometer, antennas and electronic circuitry that processes measurement data as well as controls all operations of energy conversion, propagation, and detection and wireless communications. The sensored head **407** or instrument **400** can be positioned on or within, or engaged with, or attached or affixed to or within, a wide range of physical systems including, but not limited to instruments, appliances, vehicles, equipments, or other physical systems as well as animal and human bodies, for sensing and communicating parameters of interest in real time.

An example of using the spinal instrument **400** is in the installation of a spinal cage. The spinal cage is used to space vertebrae in replacement of a disc. The spinal cage is typically hollow and can be formed having threads for fixation. Two or more cages are often installed between the vertebrae to provide sufficient support and distribution of loading over the range of motion. In one embodiment, the spinal cage is made titanium for lightweight and strength. A bone growth material can also be placed in the cage to initiate and promote bone growth thereby further strengthening the intervertebral area long-term. The spinal instrument **400** is inserted in the gap between vertebrae to measure load and position of load. The position of load corresponds to the vertebral area or surfaces applying the load on the surfaces **403** or **406** of sensored head **407**. The angle and position of insertion of the sensored head **407** of spinal instrument **400** can also be measured. The load magnitude and position of load measurement are used by the surgeon to determine an implant location between the vertebrae and the optimal size of the spinal cage for the implant location. The optimal size will be a cage height that when loaded by the spine falls within a predetermined load range. Typically, the height of sensored head **407** used to distract and measure force applied by the vertebrae of interest is equal to the cage height implanted in a subsequent step. After removing the sensored head **407** from the vertebrae the spinal cage can be implanted in the same region. The loading on the implanted spinal cage is approximately equal to the measurements made by spinal instrument **400** and applied to sensor head **407**. In one embodiment, the angle and position of the insertion trial measurement is recorded by spinal instrument **400** or a remote system coupled thereto. The angle and position measurements are subsequently used to guide the spinal cage into the same region of the spine in an identical path as spinal instrument **400** during a measurement process.

FIG. **8** illustrates an integrated sensorized spinal instrument **410** in a non-limiting example. In particular, the electronic assembly **401** is internal to the integrated instrument **410**. It includes an external wireless energy source **414** that can be placed in proximity to a charging unit to initiate a wireless power recharging operation. The wireless energy source **414** can include a power supply, a modulation circuit, and a data input. The power supply can be a battery, a charging device, a capacitor, a power connection, or other energy source for generating wireless power signals that can transfer power to spinal instrument **410**. The external wireless energy source **414** can transmit energy in the form of, but not limited to, electromagnetic induction, or other electromagnetic or ultrasound emissions. In at least one exemplary embodiment, the wireless energy source includes a coil to electromagnetically couple and activate (e.g., power on) with an induction coil in sensing device when placed in close proximity.

The electronic assembly **401** transmits measured parameter data to a receiver via data communications circuitry for permitting visualization of the level and distribution of the parameter at various points on the vertebral components. The data input can also be an interface or port to receive the input information from another data source, such as from a computer via a wired or wireless connection (e.g., USB, IEEE802.16, etc.). The modulation circuitry can modulate the input information onto the power signals generated by the power supply. Sensored head **407** has wear surfaces that are typically made of a low friction polymer material. Ideally, the sensored head **407** when inserted between vertebrae has an appropriate loading, alignment, and balance similar that is similar to a natural spine.

FIG. **9** illustrates an insert instrument **420** with vertebral components in a non-limiting example. Electronic assembly **401** as described herein similarly supports the generation of orientation and position data of insert instrument **420**. By way of the alignment system **100**, the user can replicate the insertion angle, position and trajectory (path) to achieve proper or pre-planned placement of the vertebral component. Alternatively, an accelerometer in electronic assembly **401** can provide location and trajectory information. Insert instrument **420** comprises a handle **432**, a neck **434**, and a tip **451**. An attach/release mechanism **455** couples to the proximal end of neck **434** for controlling tip **451**. Attach/release mechanism **455** allows a surgeon to retain or release vertebral components coupled to tip **451**. In the example, handle **432** extends at an angle in proximity to a proximal end of neck **434**. Positioning of handle **432** allows the surgeon to accurately direct tip **451** in a spinal region while allowing access to attach/release mechanism **455**.

In a first example, the vertebral component is a spine cage **475**. The spine cage **475** is a small hollow cylindrical device, usually made of titanium, with perforated walls that can be inserted between the vertebrae of the spine during a surgery. In general, a distraction process spaces the vertebrae to a predetermined distance prior insertion of spine cage **475**. Spine cage **475** can increase stability, decrease vertebral compression, and reduce nerve impingement as a solution to improve patient comfort. Spine cage **475** can include surface threads that allow the cage to be self-tapping and provide further stability. Spine cage **475** can be porous to include bone graft material that supports bone growth between vertebral bodies through cage **475**. More than one spine cage can be placed between vertebrae to alleviate discomfort. Proper placement and positioning of spine cage **475** is important for successful long-term implantation and patient outcome.

In a second example, the vertebral component is a pedicle screw **478**. The pedicle screw **478** is a particular type of bone screw designed for implantation into a vertebral pedicle. There are two pedicles per vertebra that couple to other structures (e.g. lamina, vertebral arch). A polyaxial pedicle screw may be made of titanium to resist corrosion and increase component strength. The pedicle screw length ranges from 30 mm to 60 mm. The diameter ranges from 5.0 mm to 8.5 mm. It is not limited to these dimensions, which serve as dimensional examples. Pedicle screw **478** can be used in instrumentation procedures to affix rods and plates to the spine to correct deformity, and/or treat trauma. It can be used to immobilize part of the spine to assist fusion by holding bony structures together. By way of electronic assembly **401** (which may be internally or externally integrated), the insert instrument **420** can determine depth and angle for screw placement and guide the screw therein. In the example, one or more accelerometers are used to provide orientation, rotation, angle, or position information of tip **451** during an insertion process.

In one arrangement, the screw **478** is embedded with sensors. The sensors can transmit energy and obtain a density reading and monitor the change in density over time. As one example, the system **100** can thus monitor and report healing of a fracture site. The sensors can detect the change in motion at the fracture site as well as the motion between the screw and bone. Such information aids in monitoring healing and gives the healthcare provider an ability to monitor vertebral weight bearing as indicated. The sensors can also be activated externally to send energy waves to the fracture itself to aid in healing.

FIG. **10** illustrates a perspective view of the spinal instrument **400** positioned between vertebrae of the spine for sensing vertebral parameters in a non-limiting example. In general, a compressive force is applied to surfaces **403** and **406** when sensored head **407** is inserted into the spinal region. In one embodiment, sensored head **407** includes two or more load sensors that identify magnitude vectors of loading on surface **403**, surface **406**, or both associated with inter-vertebral force there between. In the example shown, the spinal instrument **400** is positioned between vertebra (L5) and the Sacrum (S) such that a compressive force is applied to surfaces **403** and **406**. One approach for inserting the instrument **400** is from the posterior (back side) through a minilaparotomy as an endoscopic approach may be difficult to visualize or provide good exposure. Another approach is from the anterior (front side) which allows the surgeon to work through the abdomen to reach the spine. In this way spine muscles located in the back are not damaged or cut; avoiding muscle weakness and scarring. Spinal instrument **400** can be used with either the anterior or posterior spine approach.

Aspects of the sensorized components of the spine instrument **400** are disclosed in U.S. patent application Ser. No. 12/825,638 entitled "System and Method for Orthopedic Load Sensing Insert Device" filed Jun. 29, 2010, and U.S. patent application Ser. No. 12/825,724 entitled "Wireless Sensing Module for Sensing a Parameter of the Muscular-Skeletal System" filed Jun. 29, 2010 the entire contents of which are hereby incorporated by reference. Briefly, the sensored head **407** can measure forces (Fx, Fy, and Fz) with corresponding locations and torques (e.g. Tx, Ty, and Tz) and edge loading of vertebrae. The electronic circuitry **401** (not shown) controls operation and measurements of the sensors in sensored head **407**. The electronic circuitry **401** further includes communication circuitry for short-range data transmission. It can then transmit the measured data to the remote system to provide real-time visualization for assisting the surgeon in identifying any adjustments needed to achieve optimal joint balancing.

A method of installing a component in the muscular-system is disclosed below. The steps of the method can be performed in any order. An example of placing a cage between vertebrae is used to demonstrate the method but the method is applicable to other muscular-skeletal regions such as the knee, hip, ankle, spine, shoulder, hand, arm, and foot. In a first step, a sensored head of a predetermined width is placed in a region of the muscular-skeletal system. In the example, the insertion region is between vertebrae of the spine. A hammer can be used to tap an end of the handle to provide sufficient force to insert the sensored head between the vertebrae. The insertion process can also distract the vertebrae thereby increasing a separation distance. In a second step, the position of the load applied to the sensored head is measured. Thus, the load magnitude and the position of the loading on the surfaces of the sensored head are available. How the load applied by the muscular-skeletal system is positioned on the surfaces of the sensored head can aid in determining stability of the component once inserted. An irregular loading applied to sensored head can predict a scenario where the applied forces thrust the component away from the inserted position. In general, the sensored head is used to identify a suitable location for insertion of the component based on quantitative data. In a third step, the load and position of load data from the sensored head is displayed on a remote system in real-time. Similarly, in a fourth step, the at least one of orientation, rotation, angle, or position is displayed on the remote system in real-time. Changes made in positioning the sensored head are reflected in data on the remote system display. In a fifth step, a location between vertebrae having appropriate loading and position is identified and the corresponding quantitative measurement data is stored in memory.

In a sixth step, the sensored head is removed. In a seventh step, the component is inserted in the muscular-skeletal system. As an example, the stored quantitative measurement data is used to support the positioning of the component in the muscular-skeletal system. In the example, the insertion instrument can be used to direct the component into the muscular-skeletal system. The insertion instrument is an active device providing orientation, rotation, angle, or position of the component as it is being inserted. The previously measured direction and location of the insertion of the sensored head can be used to guide the insertion instrument. In one embodiment, the remote system display can aid in displaying relational alignment of the insertion instrument and component to the previously inserted sensored head. The insertion instrument in conjunction with the system can provide visual, vocal, haptic or other feedback to further aid in directing the placement of the component. In general, the component being inserted has substantially equal height as the sensored head. Ideally, the component is inserted identical in location and position to the previously inserted sensored head such that the loading and position of load on the component is similar to the quantitative measurements. In an eighth step, the component is positioned identically to the previously inserted sensored head and released. The insertion instrument can then be removed from the muscular-skeletal system. In a ninth step, at least the sensored head is disposed of.

Thus, the sensored head is used to identify a suitable location for insertion of the component. The insertion is supported by quantitative measurements that include position and location. Furthermore, the approximate loading and position of loading on the component is known after the procedure has been completed. In general, knowing the load applied by the muscular-skeletal system and the position on the surfaces of the component can aid in determining stability of the component long-term. An irregular loading applied on the component can result in the applied forces thrusting the component away from the inserted position.

FIG. **11** illustrates a graphical user interface (GUI) **500** showing a perspective view of the sensorized spinal instrument of FIG. **10** in a non-limiting example. The user interface **500** is presented by way of the remote system **105** and alignment system **100** (see FIG. **1**). The GUI **500** includes a window **510** and a related window **520**. The window **520** shows the spine instrument **400** and sensor head **407** in relation to a vertebra **522** under evaluation. In this example, a perspective (top) view of the vertebra is shown. It indicates a shaft angle **523** and a rotation component **524** which reveal the approach angle and rotation of the spine instrument **400**, for instance, as it is moved forward into the incision. The window **520** and corresponding GUI information is presented and updated in real-time during the procedure. It permits the surgeon to visualize use of the spine instrument **400** and the sensed parameters. The window **510** shows a sensing surface (**403** or **406**) of the sensored head **407**. A cross hair **512** is superimposed on the sensor head image to identify the maximal point of force and location. It can also lengthen to show vertebral edge loading. A window **513** reports the load force, for example, 20 lbs across the sensor head surface. This information is presented and updated in real-time during the procedure.

As previously noted, the system **100** can be used intra-operatively to aid in the implantation of the prosthesis/instrumentation/hardware by way of parameter sensing (e.g., vertebral load, edge loading, compression, etc.). The components such as receiver **101**, plurality of wands **103**, and spinal instrument **400** remain within the surgical field when used. The remote system **105** is typically outside the surgical field. All measurements are made within the surgical field by these components. In one embodiment, at least one of the receiver **101**, plurality of wands **103**, and spinal instrument are disposed of after the procedure is completed. In general, they are designed to be powered for a single use and cannot be re-sterilized.

In the spine, the affects on the bony and soft tissue elements are evaluated by the system **100**, as well as the soft tissue (e.g., cartilage, tendon, ligament) changes during surgery, including corrective spine surgery. The sensors are then used during the operation (and post-operatively) to evaluate and visualize changes over time and dynamic changes. The sensors can be activated intra-operatively when surgical parameter readings are stored. Immediately post-operatively, the sensor is activated and a baseline is known.

The sensor system **100** allows evaluation of the spine and connective tissue regarding, but not limited to bone density, fluid viscosity, temperature, strain, pressure, angular deformity, vibration, load, torque, distance, tilt, shape, elasticity, and motion. Because the sensors span a vertebral space, they can predict changes in the vertebral component function prior to their insertion. As previously noted, the system **100** is used to place the spine instrument **400** in the inter-vertebral space, where it is shown positioned relative to the vertebral body **522**. Once it is placed and visually confirmed in the vertebral center, the system **100** reports any edge loading on the instrument which in turn is used to size a proper vertebral device and insertion plan (e.g., approach angle, rotation, depth, path trajectory). Examples of implant component function include bearing wear, subsidence, bone integration, normal and abnormal motion, heat, change in viscosity, particulate matter, kinematics, to name a few.

FIG. **12** illustrates the sensorized spinal instrument **400** positioned between vertebra of the spine for intervertebral position and force sensing in a non-limiting example. As shown, sensored head **407** of spinal instrument **400** is placed between vertebrae a L4 and L5 vertebrae. The spinal instrument **400** distracts the L4 and L5 vertebrae the height of sensored head **407** and provides quantitative data on load magnitude and position of load. In one embodiment, spinal instrument **400** communicates with a first wand **510** and a second wand **520** positioned adjacent on each side thereof. A long shaft **514** is provided on each wand to permit placement within vertebra of the spine and also line up with other wands and an electronic assembly **401** of the spine instrument **400**. Wand **510** tracks an orientation and position of vertebra L4, while wand **520** tracks an orientation and position of vertebra L5. This permits the system **100** to track an orientation and movement of the spine instrument **400** relative to movement of the neighboring vertebra. Each wand is sensorized similar to the spine instrument **400**. Wand **510** and wand **520** respectively includes a sensor **512** and a sensor **513**. Sensors **512** and **513** can transmit and receive positional information. The electronic assembly **401** in conjunction with wands **510** and **520** dually serves to resolve an orientation and position of the spine instrument **400** during the procedure. One example of an ultrasonic positional sensing is disclosed in U.S. patent application Ser. No. 12/764,072 entitled "Method and System for Positional Measurement" filed Apr. 20, 2010 the entire contents of which are hereby incorporated by reference.

FIG. **13** illustrates a perspective view of a user interface **600** showing the sensorized spinal instrument of FIG. **12** in a non-limiting example. User interface **600** is presented by way of the remote system **105** and alignment system **100** (see FIG. **1**). The GUI **600** includes a first window **610** and a related second window **620**. The second window **620** shows the spine instrument and sensored head **407** in relation to a vertebral component **622** under evaluation. In this example, a sagital (side) view of the spine column is shown. It indicates a shaft angle **623** and a rotation component **624** which reveal the approach angle and rotation of the spine instrument and sensored head **407**. The second window **620** and corresponding GUI information is presented and updated in real-time during the procedure. It permits the surgeon to visualize the sensored head **407** of the spinal instrument **400** and the sensed load force parameters. The first window **610** shows a sensing surface of the sensor head (see FIG. **7**). A cross hair **612** is superimposed on the image of sensored head **407** to identify the maximal point of force and location. It can also adjust in width and length to show vertebral edge loading. Another GUI window **613** reports the load force across the sensored head **407** surface. The GUI **600** is presented and updated in real-time during the procedure.

FIG. **14** illustrates a perspective view of sensorized spinal insert instrument **420** for placement of spine cage **475** in a non-limiting example. Insert instrument **420** provides a surgical means for implanting vertebral component **475** (e.g. spine cage, pedicle screw, sensor) between the L4 and L5 vertebrae in the illustration. Mechanical assembly tip **451** at the distal end of neck **434** permits attaching and releasing of the vertebral component by way of attach/release mechanism **455**. The vertebral component **475** can be placed in the back of the spine through a midline incision in the back, for example, via posterior lumbar interbody fusion (PLIF) as shown. The insert instrument **420** can similarly be used in anterior lumbar interbody fusion (ALIF) procedures.

In one method herein contemplated, the position of the cage prior to insertion is optimally defined for example, via 3D imaging or via ultrasonic navigation as described with the wands **510** and **520** with spinal instrument **400** shown in FIGS. **12** and **13**. The load sensor **407** (see FIG. **12**) is positioned between the vertebra to assess loading forces as described above where an optimal insertion path and trajectory is therein defined. The load forces and path of instrument insertion are recorded. Thereafter as shown in FIG. **14**, the insert instrument **420** inserts the final spinal cage **475** according to the recorded path and as based on the load forces. During the insertion the GUI as shown in FIG. **15** navigates the spinal instrument **420** to the recorded insertion point. Spinal insert instrument **420** can be equipped with one or more load sensors serving as a placeholder to a final spinal cage. After placement of spinal cage **475** between the vertebra, release of the spine cage from insert instrument **420**, and removal of the insert instrument **420**, the open space occupied around the spinal cage is then closed down via rods and pedicle screws on the neighboring vertebra. This compresses the surrounding vertebra onto the spinal cage, and provides stability for verterbral fusion. During this procedure, the GUI **700** of FIG. **15** reports change in spinal anatomy, for example, Lordosis and Kyphosis, due to adjustment of the rods and tightening of the pedicle screws. Notably, the GUI **700** also provides visual feedback indicating which the amount and directions to achieve the planned spinal alignment by way of instrumented adjustments to the rods and screws.

FIG. **15** illustrates user interface **700** showing a perspective view of the sensorized spinal insert instrument **420** of FIG. **14** in a non-limiting example. The user interface **700** is presented by way of the remote system **105** and alignment system **100** (see FIG. **1**). The GUI **700** includes a first window **710** and a related second window **720**. The second window **720** shows insert instrument **420** and vertebral component **475** in relation to the L4 and L5 vertebrae under evaluation. In this example, a sagital (side) view of the spine column is shown. It indicates a shaft angle **723** and a rotation component **724** which reveal the approach angle and rotation of the insert instrument **420** and vertebral component **475**. The second window **720** and corresponding GUI information is presented and updated in real-time during the procedure. It permits the surgeon to visualize the vertebral component **475** of the insert instrument **420** according to the previously sensed load force parameters.

The first window **710** shows a target (desired) sensored head orientation **722** and a current instrument head orientation **767**. The target orientation **722** shows the approach angle, rotation and trajectory path previously determined when the spine instrument **400** was used for evaluating loading parameters. The current instrument head orientation **767** shows tracking of the insert instrument **420** currently used to insert the final cage **475**. The GUI **700** presents the target orientation model **722** in view of the current instrument head orientation **767** to provide visualization of the previously determined surgical plan.

Recall, FIGS. **10**, **11**, **12**, and **13** illustrated the spine instrument **400** assessed optimal procedural parameters (e.g., angle, rotation, path) in view of determined sensing parameters (e.g., load, force, edge). Once these procedural parameters were determined, the system **100** by way of the GUI **700** now guides the surgeon with the insert instrument **420** to insert the vertebral components **475** (e.g., spine cage, pedicle screw). In one arrangement, the system **100** provides haptic feedback to guide the insert instrument **420** during the insertion procedure. For example, it vibrates when the current approach angle **713** deviates from the target approach angle, provides a visual cue (red/green indication), or when the orientation **767** is not aligned with the target trajectory path **722**. Alternatively, vocal feedback can be provided by system **100** to supplement the visual information being provided. The GUI **700** effectively recreates the position and target path on the sensorized insert instrument **420** through visual and haptic feedback based on the previous instrumenting.

The loading, balance, and position can be adjusted during surgery within predetermined quantitatively measured ranges through surgical techniques and adjustments using data from the sensorized devices (e.g., **101**, **103**, **400**, **420**, **475**) of the alignment and load balance system **100**. Both the trial and final inserts (e.g., spine cage, pedicle screw, sensors, etc.) can include the sensing module to provide measured data to the remote system for display. A final insert can also be used to monitor the vertebral joint long term. The data can be used by the patient and health care providers to ensure that the vertebral joint or fused vertebrae is functioning properly during rehabilitation and as the patient returns to an active normal lifestyle. Conversely, the patient or health care provider can be notified when the measured parameters are out of specification. This provides early detection of a spine problem that can be resolved with minimal stress to the patient. The data from final insert can be displayed on a screen in real time using data from the embedded sensing module. In one embodiment, a handheld device is used to receive data from final insert. The handheld device can be held in proximity to the spine allowing a strong signal to be obtained for reception of the data.

A method of distracting a spinal region is disclosed below. The steps of the method can be performed in any order. Reference can be made to FIG. **10**, FIG. **11**, FIG. **12**, FIG. **13**, and FIG. **14**. An example of placing a prosthetic component such as a spinal cage between vertebrae is used to demonstrate the method but the method is applicable to other muscular-skeletal regions such as the knee, hip, ankle, spine, shoulder, hand, arm, and foot. In general, quantitative measurement data needs to be collected on the spine region. The spinal instrument, alignment devices, and insert instrument disclosed herein can be used to generate a database of quantitative data. At this time there is a dearth of quantitative measurement data due to the lack of active tools and measurement devices. The measurement data generated by the tools during prosthetic component installation can be correlated with other short-term and long-term data to determine the effect of load, position of load, and prosthetic component alignment as it relates to patient health. The system disclosed herein can generate data during prosthetic component installation and is applicable for providing long-term periodic measurement of the implant and spinal region. Thus, the result of the distraction method is to generate sufficient data that supports an installation procedure that reduces recovery time, minimizes failures, improves performance, reliability, and extends device life expectancy.

In a first step, a spinal instrument is inserted to distract the spinal region. The spinal instrument includes sensors for generating quantitative measurement data in real-time during surgery. In a second step, a load applied by the spinal region to the spinal instrument is measured. The spinal instrument has a first height such that the spinal region is distracted to the first height. The system indicates measurement data by visual, audio, or haptic means. In one example, the system discloses that the load measurement from the spinal instrument is outside a predetermined load range. The predetermined load range used by the system to assess the spinal region can be determined by clinical study. For example, the predetermined load range can support device installation by correlating load measurement data to outcomes of the surgical procedure. In general, a measurement outside the predetermined load range may statistically increase a chance of device failure. In a third step, the spinal region is distracted to a second height. In a fourth step, the load applied by the spinal region to the spinal instrument at the second height is measured. The system indicates that the load measurement from the spinal instrument is within the predetermined load range. Having the measured load within the predetermined load range reduces failures due to excessive loading on the prosthetic component. In general, the process can be repeated as many times as required at different distraction heights until the spinal instrument measurement indicates that the measured load is within the predetermined load range.

In a fifth step, at least one of orientation, rotation, angle, or position of the spinal instrument is measured. In one embodiment, the measurement can correspond to the portion of the spinal instrument inserted in the spinal region. For example, the position data can relate to a sensored head of the spinal instrument. The data can be used to place a prosthetic component in a similar position and at the same trajectory as measured by the spinal instrument. In a sixth step, loading applied by the spinal region to the spinal instrument can be monitored on the remote system. In the example, the remote system includes a display that allows viewing of the data in real-time during the procedure. In a seventh step, the height of the spinal instrument can be adjusted. As disclosed, the spinal instrument can include a scissor type mechanism to decrease or increase height of the distraction surfaces. In one embodiment, the handle of the spinal instrument is rotated to change distraction height. The adjustment can be made while monitoring the load data on the remote system in real-time. In general, the height is adjusted until the measured load is within the predetermined load range. In an eighth step, the height is increased or decreased such that the adjusted height corresponds to a height of a prosthetic component. In one embodiment, a prosthetic component having the same distraction height can be placed in the location of the load measurement in the spinal region. The prosthetic component is loaded similarly to the load measurement when aligned to the trajectory and placed in a same location as the spinal instrument.

In a ninth step, the spinal instrument measures a position of applied load. The spinal instrument may have a surface coupled to the spinal region. In the example, more than one sensor is coupled to a surface of the spinal instrument to support position of load measurement. The position of load provides quantitative measurement data on how the force, pressure, or load would be applied to the prosthetic component when placed in the spinal region. For example, an incorrect position of load could produce a situation where the prosthetic component would be unstable in the location and eventually be forced from the spinal region causing a catastrophic failure. In one embodiment, position of load data from the spinal instrument may be used to assess the position for prosthetic component placement. The quantitative data can include a predetermined range or area that corresponds to the measurement surface of the spinal instrument for assessing position of load. In a tenth step, the spinal instrument is moved to a different location in the spinal region when the position of load applied by the spinal region to the spinal instrument is outside a predetermined position range. The new location can be assessed by load magnitude and position of load quantitative data as a site for the prosthetic component.

In an eleventh step, an appropriate location in the spinal region is identified for a prosthetic component when the measured quantitative data falls within the predetermined load range and the predetermined position range. As mentioned previously, placing the prosthetic component in an area of the spinal region measuring within the predetermined load range and the predetermined position range produces positive outcomes and lowers failure rate based on clinical evidence. In a twelfth step, the prosthetic component is placed in the location measured by the spinal instrument. The prosthetic component placed in the location will have an applied load magnitude and position of load by the spinal region similar to that measured by the spinal instrument. The prosthetic component is inserted into the spinal region having a similar trajectory as the spinal instrument. In the example, the trajectory and position of the spinal instrument during the measurement process is recorded. In a thirteenth step, the insertion process of the prosthetic component can be further supported by comparing the trajectory of the prosthetic component to the trajectory of the spinal instrument. In one embodiment, the surgeon can be provided visual, haptic, or audio feedback to aid in the alignment of the prosthetic component to the location. In a fourteenth step, the trajectories of the prosthetic component and the spinal instrument are viewed on a remote system. The remote system can show the actual or simulated position and trajectory of the prosthetic component in relation to the position and trajectory of the spinal instrument when identifying the location in the spinal region. In one embodiment, the surgeon can mimic the trajectory with a device or insert instrument that holds the prosthetic component through a visualization or overlay on the spinal instrument location data displayed on the remote system. As disclosed herein, the spinal instrument can have a mechanism such as a scissor jack that can change the height of the distracting surfaces. A rod for raising and lowering the scissor jack couples to the handle of the spinal instrument. In a fifteenth step, the handle of the spinal instrument can be rotated to change the distraction height. In a sixteenth step, a visual, audio, or haptic signal is provided when the load applied by the spinal region to the spinal instrument are within the predetermined load range. Similarly, in a seventeenth step, a visual, audio, or haptic signal is provided when the load applied by the spinal region to the spinal instrument is within the predetermined position range.

FIG. **16** is a block diagram of the components of spinal instrument **400** in accordance with an example embodiment. It should be noted that spinal instrument **400** could comprise more or less than the number of components shown. Spinal instrument **400** is a self-contained tool that can measure a parameter of the muscular-skeletal system. In the example, the spinal instrument **400** measures load and position of load when inserted in a spinal region. The active components of spinal instrument **400** include one or more sensors **1602**, a load plate **1606**, a power source **1608**, electronic circuitry **1610**, a transceiver **1612**, and an accelerometer **1614**. In a non-limiting example, an applied compressive force is applied to sensors **1602** by the spinal region and measured by the spinal instrument **400**.

The sensors **1602** can be positioned, engaged, attached, or affixed to the surfaces **403** and **406** of spinal instrument **400**. In general, a compressive force is applied by the spinal region to surfaces **403** and **406** when inserted therein. The surfaces **403** and **406** couple to sensors **1602** such that a compressive force is applied to each sensor. In one embodiment, the position of applied load to surfaces **403** and **406** can be measured. In the example, three load sensors are used in the sensored head to identify position of applied load. Each load sensor is coupled to a predetermined position on the load plate **1606**. The load plate **1606** couples to surface **403** to distribute a compressive force applied to the sensored head of spinal instrument **400** to each sensor. The load plate **1606** can be rigid and does not flex when distributing the force, pressure, or load to sensors **1606**. The force or load magnitude measured by each sensor can be correlated back to a location of applied load on the surface **403**.

In the example of intervertebral measurement, the sensored head having surfaces **403** and **406** can be positioned between the vertebrae of the spine. Surface **403** of the sensored head couples to a first vertebral surface and similarly the surface **406** couples to a second vertebral surface. Accelerometer **1614** or an external alignment system can be used to measure position and orientation of the sensored head as it is directed into the spinal region. The sensors **1602** couple to the electronic circuitry **1610**. The electronic circuitry **1610** comprises logic circuitry, input/output circuitry, clock circuitry, D/A, and A/D circuitry. In one embodiment, the electronic circuitry **1610** comprises an application specific integrated circuit that reduces form factor, lowers power, and increases performance. In general, the electronic circuitry **1610** controls a measurement process, receives the measurement signals, converts the measurement signals to a digital form, supports display on an interface, and initiates data transfer of measurement data. Electronic circuitry **1610** measures physical changes in the sensors **1602** to determine parameters of interest, for example a level, distribution and direction of forces acting on the surfaces **403** and **406**. The insert sensing device **400** can be powered by an internal power source **1608**. Thus, all the components required to measure parameters of the muscular-skeletal system reside in the spinal instrument **400**.

As one example, sensors **1602** can comprise an elastic or compressible propagation structure between a first transducer and a second transducer. The transducers can be an ultrasound (or ultrasonic) resonator, and the elastic or compressible propagation structure can be an ultrasound waveguide. The electronic circuitry **1610** is electrically coupled to the transducers to translate changes in the length (or compression or extension) of the compressible propagation structure to parameters of interest, such as force. The system measures a change in the length of the compressible propagation structure (e.g., waveguide) responsive to an applied force and converts this change into electrical signals, which can be transmitted via the transceiver **1612** to convey a level and a direction of the applied force. For example, the compressible propagation structure has known and repeatable characteristics of the applied force versus the length of the waveguide. Precise measurement of the length of the waveguide using ultrasonic signals can be converted to a force using the known characteristics.

Sensors **1602** are not limited to waveguide measurements of force, pressure, or load sensing. In yet other arrangements, sensors **1602** can include piezo-resistive, compressible polymers, capacitive, optical, mems, strain gauge, chemical, temperature, pH, and mechanical sensors for measuring parameters of the muscular-skeletal system. In an alternate embodiment, a piezo-resistive film sensor can be used for sensing load. The piezo-resistive film has a low profile thereby reducing the form factor required for the implementation. The piezo-resistive film changes resistance with applied pressure. A voltage or current can be applied to the piezo-resistive film to monitor changes in resistance. Electronic circuitry **1610** can be coupled to apply the voltage or current. Similarly, electronic circuitry **1610** can be coupled to measure the voltage and current corresponding to a resistance of the piezo-resistive film. The relation of piezo-resistive film resistance to an applied force, pressure, or load is known. Electronic circuitry **1610** can convert the measured voltage or current to a force, pressure, or load applied to the sensored head. Furthermore, electronic circuitry **1610** can convert the measurement to a digital format for display or transfer for real-time use or for being stored. Electronic circuitry **1610** can include converters, inputs, outputs, and input/outputs that allow serial and parallel data transfer whereby measurements and transmission of data can occur simultaneously. In one embodiment, an ASIC is included in electronic circuitry **1610** that incorporates digital control logic to manage control functions and the measurement process of spinal instrument **400** as directed by the user.

The accelerometer **1614** can measure acceleration and static gravitational pull. Accelerometer **1614** can be single-axis and multi-axis accelerometer structures that detect magnitude and direction of the acceleration as a vector quantity. Accelerometer **1614** can also be used to sense orientation, vibration, impact and shock. The electronic circuitry **1610** in conjunction with the accelerometer **1614** and sensors **1602** can measure parameters of interest (e.g., distributions of load, force, pressure, displacement, movement, rotation, torque, location, and acceleration) relative to orientations of spinal instrument **400**. In such an arrangement, spatial distributions of the measured parameters relative to a chosen frame of reference can be computed and presented for real-time display.

The transceiver **1612** comprises a transmitter **1622** and an antenna **1620** to permit wireless operation and telemetry functions. In various embodiments, the antenna **1620** can be configured by design as an integrated loop antenna. The integrated loop antenna is configured at various layers and locations on a printed circuit board having other electrical components mounted thereto. For example, electronic circuitry **1610**, power source **1608**, transceiver **1612**, and accelerometer **1614** can be mounted on a circuit board that is located on or in spinal instrument **400**. Once initiated the transceiver **1612** can broadcast the parameters of interest in real-time. The telemetry data can be received and decoded with various receivers, or with a custom receiver. The wireless operation can eliminate distortion of, or limitations on, measurements caused by the potential for physical interference by, or limitations imposed by, wiring and cables coupling the sensing module with a power source or with associated data collection, storage, display equipment, and data processing equipment.

The transceiver **1612** receives power from the power source **1608** and can operate at low power over various radio frequencies by way of efficient power management schemes, for example, incorporated within the electronic circuitry **1610** or the application specific integrated circuit. As one example, the transceiver **1612** can transmit data at selected frequencies in a chosen mode of emission by way of the antenna **1620**. The selected frequencies can include, but are not limited to, ISM bands recognized in International Telecommunication Union regions 1, 2 and 3. A chosen mode of emission can be, but is not limited to, Gaussian Frequency Shift Keying, (GFSK), Amplitude Shift Keying (ASK), Phase Shift Keying (PSK), Minimum Shift Keying (MSK), Frequency Modulation (FM), Amplitude Modulation (AM), or other versions of frequency or amplitude modulation (e.g., binary, coherent, quadrature, etc.).

The antenna **1620** can be integrated with components of the sensing module to provide the radio frequency transmission. The antenna **1620** and electronic circuitry **1610** are mounted and coupled to form a circuit using wire traces on a printed circuit board. The antenna **1620** can further include a matching network for efficient transfer of the signal. This level of integration of the antenna and electronics enables reductions in the size and cost of wireless equipment. Potential applications may include, but are not limited to any type of short-range handheld, wearable, or other portable communication equipment where compact antennas are commonly used. This includes disposable modules or devices as well as reusable modules or devices and modules or devices for long-term use.

The power source **1608** provides power to electronic components of the spinal instrument **400**. In one embodiment, power source **1608** can be charged by wired energy transfer, short-distance wireless energy transfer or a combination thereof. External power sources for providing wireless energy to power source **1608** can include, but are not limited to, a battery or batteries, an alternating current power supply, a radio frequency receiver, an electromagnetic induction coil, a photoelectric cell or cells, a thermocouple or thermocouples, or an ultrasound transducer or transducers. By way of power source **1608**, spinal instrument **400** can be operated with a single charge until the internal energy is drained. It can be recharged periodically to enable continuous operation. The power source **1608** can further utilize power management techniques for efficiently supplying and providing energy to the components of spinal instrument **400** to facilitate measurement and wireless operation. Power management circuitry can be incorporated on the ASIC to manage both the ASIC power consumption as well as other components of the system.

The power source **1608** minimizes additional sources of energy radiation required to power the sensing module during measurement operations. In one embodiment, as illustrated, the energy storage **1608** can include a capacitive energy storage device **1624** and an induction coil **1626**. The external source of charging power can be coupled wirelessly to the capacitive energy storage device **1624** through the electromagnetic induction coil or coils **1626** by way of inductive charging. The charging operation can be controlled by a power management system designed into, or with, the electronic circuitry **1610**. For example, during operation of electronic circuitry **1610**, power can be transferred from capacitive energy storage device **1624** by way of efficient step-up and step-down voltage conversion circuitry. This conserves operating power of circuit blocks at a minimum voltage level to support the required level of performance. Alternatively, power source **1608** can comprise one or more batteries that are housed within spinal instrument **400**. The batteries can power a single use of the spinal instrument **400** whereby the device is disposed after it has been used in a surgery.

In one configuration, the external power source can further serve to communicate downlink data to the transceiver **1612** during a recharging operation. For instance, downlink control data can be modulated onto the wireless energy source signal and thereafter demodulated from the induction coil **1626** by way of electronic circuitry **1610**. This can serve as a more efficient way for receiving downlink data instead of configuring the transceiver **1612** for both uplink and downlink operation. As one example, downlink data can include updated control parameters that the spinal instrument **400** uses when making a measurement, such as external positional information, or for recalibration purposes. It can also be used to download a serial number or other identification data.

The electronic circuitry **1610** manages and controls various operations of the components of the sensing module, such as sensing, power management, telemetry, and acceleration sensing. It can include analog circuits, digital circuits, integrated circuits, discrete components, or any combination thereof. In one arrangement, it can be partitioned among integrated circuits and discrete components to minimize power consumption without compromising performance. Partitioning functions between digital and analog circuit enhances design flexibility and facilitates minimizing power consumption without sacrificing functionality or performance. Accordingly, the electronic circuitry **1610** can comprise one or more integrated circuits or ASICs, for example, specific to a core signal-processing algorithm.

In another arrangement, the electronic circuitry **1610** can comprise a controller such as a programmable processor, a Digital Signal Processor (DSP), a microcontroller, or a microprocessor, with associated storage memory and logic. The controller can utilize computing technologies with associated storage memory such a Flash, ROM, RAM, SRAM, DRAM or other like technologies for controlling operations of the aforementioned components of the sensing module. In one arrangement, the storage memory may store one or more sets of instructions (e.g., software) embodying any one or more of the methodologies or functions described herein. The instructions may also reside, completely or at least partially, within other memory, and/or a processor during execution thereof by another processor or computer system.

The electronics assemblage also supports testability and calibration features that assure the quality, accuracy, and reliability of the completed wireless sensing module or device. A temporary bi-directional coupling can be used to assure a high level of electrical observability and controllability of the electronics. The test interconnect also provides a high level of electrical observability of the sensing subsystem, including the transducers, waveguides, and mechanical spring or elastic assembly. Carriers or fixtures emulate the final enclosure of the completed wireless sensing module or device during manufacturing processing thus enabling capture of accurate calibration data for the calibrated parameters of the finished wireless sensing module or device. These calibration parameters are stored within the on-board memory integrated into the electronics assemblage.

Applications for the electronic assembly comprising the sensors **1602** and electronic circuitry **1610** may include, but are not limited to, disposable modules or devices as well as reusable modules or devices and modules or devices for long-term use. In addition to non-medical applications, examples of a wide range of potential medical applications may include, but are not limited to, implantable devices, modules within implantable devices, intra-operative implants or modules within intra-operative implants or trial inserts, modules within inserted or ingested devices, modules within wearable devices, modules within handheld devices, modules within instruments, appliances, equipment, or accessories of all of these, or disposables within implants, trial inserts, inserted or ingested devices, wearable devices, handheld devices, instruments, appliances, equipment, or accessories to these devices, instruments, appliances, or equipment.

FIG. **17** is a diagram of an exemplary communications system **1700** for short-range telemetry in accordance with an exemplary embodiment. As illustrated, the communications system **1700** comprises medical device communications components **1710** in a spinal instrument and receiving system communications in a processor based remote system. In one embodiment, the receiving remote system communications are in or coupled to a computer or laptop computer that can be viewed by the surgical team during a procedure. The remote system can be external to the sterile field of the operating room but within viewing range to assess measured quantitative data in real time. The medical device communications components **1710** are operatively coupled to include, but not limited to, the antenna **1712**, a matching network **1714**, a telemetry transceiver **1716**, a CRC circuit **1718**, a data packetizer **1722**, a data input **1724**, a power source **1726**, and an application specific integrated circuit (ASIC) **1720**. The medical device communications components **1710** may include more or less than the number of components shown and are not limited to those shown or the order of the components.

The receiving station communications components **1750** comprise an antenna **1752**, a matching network **1754**, a telemetry receiver **1756**, the CRC circuit **1758**, the data packetizer **1760**, and optionally a USB interface **1762**. Notably, other interface systems can be directly coupled to the data packetizer **1760** for processing and rendering sensor data.

Referring to FIG. **16**, the electronic circuitry **1610** is operatively coupled to one or more sensors **602** of the spinal instrument **400**. In one embodiment, the data generated by the one or more sensors **602** can comprise a voltage, current, frequency, or count from a mems structure, piezo-resistive sensor, strain gauge, mechanical sensor, pulsed, continuous wave, or other sensor type that can be converted to the parameter being measured of the muscular-skeletal system. Referring back to FIG. **17**, the data packetizer **1722** assembles the sensor data into packets; this includes sensor information received or processed by ASIC **1720**. The ASIC **1720** can comprise specific modules for efficiently performing core signal processing functions of the medical device communications components **1710**. The ASIC **1720** further provides the benefit of reducing a form factor of the tool.

The CRC circuit **1718** applies error code detection on the packet data. The cyclic redundancy check is based on an algorithm that computes a checksum for a data stream or packet of any length. These checksums can be used to detect interference or accidental alteration of data during transmission. Cyclic redundancy checks are especially good at detecting errors caused by electrical noise and therefore enable robust protection against improper processing of corrupted data in environments having high levels of electromagnetic activity. The telemetry transmitter **1716** then transmits the CRC encoded data packet through the matching network **1714** by way of the antenna **1712**. The matching networks **1714** and **1754** provide an impedance match for achieving optimal communication power efficiency.

The receiving system communications components **1750** receive transmissions sent by spinal instrument communications components **1710**. In one embodiment, telemetry transmitter **1716** is operated in conjunction with a dedicated telemetry receiver **1756** that is constrained to receive a data stream broadcast on the specified frequencies in the specified mode of emission. The telemetry receiver **1756** by way of the receiving station antenna **1752** detects incoming transmissions at the specified frequencies. The antenna **1752** can be a directional antenna that is directed to a directional antenna of components **1710**. Using at least one directional antenna can reduce data corruption while increasing data security by further limiting the data is radiation pattern. A matching network **1754** couples to antenna **1752** to provide an impedance match that efficiently transfers the signal from antenna **1752** to telemetry receiver **1756**. Telemetry receiver **1756** can reduce a carrier frequency in one or more steps and strip off the information or data sent by components **1710**. Telemetry receiver **1756** couples to CRC circuit **1758**. CRC circuit **1758** verifies the cyclic redundancy checksum for individual packets of data. CRC circuit **1758** is coupled to data packetizer **1760**. Data packetizer **1760** processes the individual packets of data. In general, the data that is verified by the CRC circuit **1758** is decoded (e.g., unpacked) and forwarded to an external data processing device, such as an external computer, for subsequent processing, display, or storage or some combination of these.

The telemetry receiver **1756** is designed and constructed to operate on very low power such as, but not limited to, the power available from the powered USB port **1762**, or a battery. In another embodiment, the telemetry receiver **1756** is designed for use with a minimum of controllable functions to limit opportunities for inadvertent corruption or malicious tampering with received data. The telemetry receiver **1756** can be designed and constructed to be compact, inexpensive, and easily manufactured with standard manufacturing processes while assuring consistently high levels of quality and reliability.

In one configuration, the communication system **1700** operates in a transmit-only operation with a broadcasting range on the order of a few meters to provide high security and protection against any form of unauthorized or accidental query. The transmission range can be controlled by the transmitted signal strength, antenna selection, or a combination of both. A high repetition rate of transmission can be used in conjunction with the Cyclic Redundancy Check (CRC) bits embedded in the transmitted packets of data during data capture operations thereby enabling the receiving system to discard corrupted data without materially affecting display of data or integrity of visual representation of data, including but not limited to measurements of load, force, pressure, displacement, flexion, attitude, and position within operating or static physical systems.

By limiting the operating range to distances on the order of a few meters the telemetry transmitter **1716** can be operated at very low power in the appropriate emission mode or modes for the chosen operating frequencies without compromising the repetition rate of the transmission of data. This mode of operation also supports operation with compact antennas, such as an integrated loop antenna. The combination of low power and compact antennas enables the construction of, but is not limited to, highly compact telemetry transmitters that can be used for a wide range of non-medical and medical applications.

The transmitter security as well as integrity of the transmitted data is assured by operating the telemetry system within predetermined conditions. The security of the transmitter cannot be compromised because it is operated in a transmit-only mode and there is no pathway to hack into medical device communications components. The integrity of the data is assured with the use of the CRC algorithm and the repetition rate of the measurements. The risk of unauthorized reception of the data is minimized by the limited broadcast range of the device. Even if unauthorized reception of the data packets should occur there are counter measures in place that further mitigate data access. A first measure is that the transmitted data packets contain only binary bits from a counter along with the CRC bits. A second measure is that no data is available or required to interpret the significance of the binary value broadcast at any time. A third measure that can be implemented is that no patient or device identification data is broadcast at any time.

The telemetry transmitter **1716** can also operate in accordance with some FCC regulations. According to section 18.301 of the FCC regulations the ISM bands within the USA include 6.78, 13.56, 27.12, 30.68, 915, 2450, and 5800 MHz as well as 24.125, 61.25, 122.50, and 245 GHz. Globally other ISM bands, including 433 MHz, are defined by the International Telecommunications Union in some geographic locations. The list of prohibited frequency bands defined in 18.303 are "the following safety, search and rescue frequency bands is prohibited: 490-510 kHz, 2170-2194 kHz, 8354-8374 kHz, 121.4-121.6 MHz, 156.7-156.9 MHz, and 242.8-243.2 MHz." Section 18.305 stipulates the field strength and emission levels ISM equipment must not exceed when operated outside defined ISM bands. In summary, it may be concluded that ISM equipment may be operated worldwide within ISM bands as well as within most other frequency bands above 9 KHz given that the limits on field strengths and emission levels specified in section 18.305 are maintained by design or by active control. As an alternative, commercially available ISM transceivers, including commercially available integrated circuit ISM transceivers, may be designed to fulfill these field strengths and emission level requirements when used properly.

In one configuration, the telemetry transmitter **1716** can also operate in unlicensed ISM bands or in unlicensed operation of low power equipment, wherein the ISM equipment (e.g., telemetry transmitter **1716**) may be operated on ANY frequency above 9 kHz except as indicated in Section 18.303 of the FCC code.

Wireless operation eliminates distortion of, or limitations on, measurements caused by the potential for physical interference by, or limitations imposed by, wiring and cables coupling the wireless sensing module or device with a power source or with data collection, storage, or display equipment. Power for the sensing components and electronic circuits is maintained within the wireless sensing module or device on an internal energy storage device. This energy storage device is charged with external power sources including, but not limited to, a battery or batteries, super capacitors, capacitors, an alternating current power supply, a radio frequency receiver, an electromagnetic induction coil, a photoelectric cell or cells, a thermocouple or thermocouples, or an ultrasound transducer or transducers. The wireless sensing module may be operated with a single charge until the internal energy source is drained or the energy source may be recharged periodically to enable continuous operation. The embedded power supply minimizes additional sources of energy radiation required to power the wireless sensing module or device during measurement operations. Telemetry functions are also integrated within the wireless sensing module or device. Once initiated the telemetry transmitter continuously broadcasts measurement data in real time. Telemetry data may be received and decoded with commercial receivers or with a simple, low cost custom receiver.

FIG. **18** illustrates a communication network **1800** for measurement and reporting in accordance with an example embodiment. Briefly, the communication network **1800** expands spinal alignment system **100**, spinal instrument **400**, and insert instrument **420** to provide broad data connectivity to other devices or services. As illustrated, spinal alignment system **100**, spinal instrument **400**, and insert instrument **420** can be communicatively coupled to the communications network **1800** and any associated systems or services.

As one example, spinal alignment system **100**, spinal instrument **400**, and insert instrument **420** can share its parameters of interest (e.g., distributions of load, force, pressure, displacement, movement, rotation, torque and acceleration) with remote services or providers, for instance, to analyze or report on surgical status or outcome. In the case that a sensor system is permanently implanted, the data from the sensor can be shared for example with a service provider to monitor progress or with plan administrators for surgical planning purposes or efficacy studies. The communication network **1800** can further be tied to an Electronic Medical Records (EMR) system to implement health information technology practices. In other embodiments, the communication network **1800** can be communicatively coupled to HIS Hospital Information System, HIT Hospital Information Technology and HIM Hospital Information Management, EHR Electronic Health Record, CPOE Computerized Physician Order Entry, and CDSS Computerized Decision Support Systems. This provides the ability of different information technology systems and software applications to communicate, to exchange data accurately, effectively, and consistently, and to use the exchanged data.

The communications network **1800** can provide wired or wireless connectivity over a Local Area Network (LAN) **1801**, a Wireless Local Area Network (WLAN) **1805**, a Cellular Network **1814**, and/or other radio frequency (RF) system. The LAN **1801** and WLAN **1805** can be communicatively coupled to the Internet **1820**, for example, through a central office. The central office can house common network switching equipment for distributing telecommunication services. Telecommunication services can include traditional POTS (Plain Old Telephone Service) and broadband services such as cable, HDTV, DSL, VoIP (Voice over Internet Protocol), IPTV (Internet Protocol Television), Internet services, and so on.

The communication network **1800** can utilize common computing and communications technologies to support circuit-switched and/or packet-switched communications. Each of the standards for Internet **1820** and other packet switched network transmission (e.g., TCP/IP, UDP/IP, HTML, HTTP, RTP, MMS, SMS) represent examples of the state of the art. Such standards are periodically superseded by faster or more efficient equivalents having essentially the same functions. Accordingly, replacement standards and protocols having the same functions are considered equivalent.

The cellular network **1814** can support voice and data services over a number of access technologies such as GSM-GPRS, EDGE, CDMA, UMTS, WiMAX, 2G, 3G, WAP, software defined radio (SDR), and other known technologies. The cellular network **1814** can be coupled to base receiver **1810** under a frequency-reuse plan for communicating with mobile devices **1802**.

The base receiver **1810**, in turn, can connect the mobile device **1802** to the Internet **1820** over a packet switched link. The internet **1820** can support application services and service layers for distributing data from spinal alignment system **100**, spinal instrument **400**, and insert instrument **420** to the mobile device **502**. The mobile device **1802** can also connect to other communication devices through the Internet **1820** using a wireless communication channel.

The mobile device **1802** can also connect to the Internet **1820** over the WLAN **1805**. Wireless Local Access Networks (WLANs) provide wireless access within a local geographical area. WLANs are typically composed of a cluster of Access Points (APs) **1804** also known as base stations. Spinal alignment system **100**, spinal instrument **400**, and insert instrument **420** can communicate with other WLAN stations such as laptop **1803** within the base station area. In typical WLAN implementations, the physical layer uses a variety of technologies such as 802.11b or 802.11g WLAN technologies. The physical layer may use infrared, frequency hopping spread spectrum in the 2.4 GHz Band, direct sequence spread spectrum in the 2.4 GHz Band, or other access technologies, for example, in the 5.8 GHz ISM band or higher ISM bands (e.g., 24 GHz, etc.).

By way of the communication network **1800**, spinal alignment system **100**, spinal instrument **400**, and insert instrument **420** can establish connections with a remote server **1830** on the network and with other mobile devices for exchanging data. The remote server **1830** can have access to a database **1840** that is stored locally or remotely and which can contain application specific data. The remote server **1830** can also host application services directly, or over the internet **1820**.

FIG. **19** depicts an exemplary diagrammatic representation of a machine in the form of a computer system **1900** within which a set of instructions, when executed, may cause the machine to perform any one or more of the methodologies discussed above. In some embodiments, the machine operates as a standalone device. In some embodiments, the machine may be connected (e.g., using a network) to other machines. In a networked deployment, the machine may operate in the capacity of a server or a client user machine in server-client user network environment, or as a peer machine in a peer-to-peer (or distributed) network environment.

The machine may comprise a server computer, a client user computer, a personal computer (PC), a tablet PC, a laptop computer, a desktop computer, a control system, a network router, switch or bridge, or any machine capable of executing a set of instructions (sequential or otherwise) that specify actions to be taken by that machine. It will be understood that a device of the present disclosure includes broadly any electronic device that provides voice, video or data communication. Further, while a single machine is illustrated, the term "machine" shall also be taken to include any collection of machines that individually or jointly execute a set (or multiple sets) of instructions to perform any one or more of the methodologies discussed herein.

The computer system **1900** may include a processor **1902** (e.g., a central processing unit (CPU), a graphics processing unit (GPU, or both), a main memory **1904** and a static memory **1906**, which communicate with each other via a bus **1908**. The computer system **1900** may further include a video display unit **1910** (e.g., a liquid crystal display (LCD), a flat panel, a solid-state display, or a cathode ray tube (CRT)). The computer system **1900** may include an input device **1912** (e.g., a keyboard), a cursor control device **1914** (e.g., a mouse), a disk drive unit **1916**, a signal generation device **1918** (e.g., a speaker or remote control) and a network interface device **1920**.

The disk drive unit **1916** may include a machine-readable medium **1922** on which is stored one or more sets of instructions (e.g., software **1924**) embodying any one or more of the methodologies or functions described herein, including those methods illustrated above. The instructions **1924** may also reside, completely or at least partially, within the main memory **1904**, the static memory **1906**, and/or within the processor **1902** during execution thereof by the computer system **1900**. The main memory **1904** and the processor **1902** also may constitute machine-readable media.

Dedicated hardware implementations including, but not limited to, application specific integrated circuits, programmable logic arrays and other hardware devices can likewise be constructed to implement the methods described herein. Applications that may include the apparatus and systems of various embodiments broadly include a variety of electronic and computer systems. Some embodiments implement functions in two or more specific interconnected hardware modules or devices with related control and data signals communicated between and through the modules, or as portions of an application-specific integrated circuit. Thus, the example system is applicable to software, firmware, and hardware implementations.

In accordance with various embodiments of the present disclosure, the methods described herein are intended for operation as software programs running on a processor, digital signal processor, or logic circuitry. Furthermore, software implementations can include, but not limited to, distributed processing or component/object distributed processing, parallel processing, or virtual machine processing can also be constructed to implement the methods described herein.

The present disclosure contemplates a machine readable medium containing instructions **1924**, or that which receives and executes instructions **1924** from a propagated signal so that a device connected to a network environment **1926** can send or receive voice, video or data, and to communicate over the network **1926** using the instructions **1924**. The instructions **1924** may further be transmitted or received over a network **1926** via the network interface device **1920**.

While the machine-readable medium **1922** is shown in an example embodiment to be a single medium, the term "machine-readable medium" should be taken to include a single medium or multiple media (e.g., a centralized or distributed database, and/or associated caches and servers) that store the one or more sets of instructions. The term "machine-readable medium" shall also be taken to include any medium that is capable of storing, encoding or carrying a set of instructions for execution by the machine and that cause the machine to perform any one or more of the methodologies of the present disclosure.

The term "machine-readable medium" shall accordingly be taken to include, but not be limited to: solid-state memories such as a memory card or other package that houses one or more read-only (non-volatile) memories, random access memories, or other re-writable (volatile) memories; magneto-optical or optical medium such as a disk or tape; and carrier wave signals such as a signal embodying computer instructions in a transmission medium; and/or a digital file attachment to e-mail or other self-contained information archive or set of archives is considered a distribution medium equivalent to a tangible storage medium. Accordingly, the disclosure is considered to include any one or more of a machine-readable medium or a distribution medium, as listed herein and including art-recognized equivalents and successor media, in which the software implementations herein are stored.

Although the present specification describes components and functions implemented in the embodiments with reference to particular standards and protocols, the disclosure is not limited to such standards and protocols. Each of the standards for Internet and other packet switched network transmission (e.g., TCP/IP, UDP/IP, HTML, HTTP) represent examples of the state of the art. Such standards are periodically superseded by faster or more efficient equivalents having essentially the same functions. Accordingly, replacement standards and protocols having the same functions are considered equivalents.

The illustrations of embodiments described herein are intended to provide a general understanding of the structure of various embodiments, and they are not intended to serve as a complete description of all the elements and features of apparatus and systems that might make use of the structures described herein. Many other embodiments will be apparent to those of skill in the art upon reviewing the above description. Other embodiments may be utilized and derived therefrom, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Figures are also merely representational and may not be drawn to scale. Certain proportions thereof may be exaggerated, while others may be minimized. Accordingly, the specification and drawings are to be regarded in an illustrative rather than a restrictive sense.

Such embodiments of the inventive subject matter may be referred to herein, individually and/or collectively, by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept if more than one is in fact disclosed. Thus, although specific embodiments have been illustrated and described herein, it should be appreciated that any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

What is claimed is:

1. A method of distracting a spinal region comprising the steps of:

inserting a sensored head of a spinal instrument into a spinal region;

electronically measuring at least one of the orientation, rotation, angle, or position of the sensor head with respect to a reference position not on the spinal instrument;

positioning the sensored head until the position of a load magnitude on the sensored head as electronically measured by the sensored head is within a predetermined positional range; and

distracting the spinal region to a height where an electrical measurement of the load magnitude by the sensored head of the spinal instrument is within a predetermined load range.

2. The method of claim **1** further including the steps of:

remote monitoring loading measured by the spinal instrument; and adjusting a height of the spinal instrument coupled to the spinal region to increase or decrease distraction of the spinal instrument until an electronically measured loading is within the predetermined load range.

3. The method of claim **2** where the step of adjusting the height includes increasing or decreasing a distraction height corresponding to heights of a prosthetic component.

4. The method of claim **3** further including a step of identifying a location in the spinal region for the prosthetic component that falls within the predetermined load range and the predetermined position range.

5. The method of claim **4** further including a step of placing the prosthetic component at the location in the spinal region.

6. The method of claim **5** further including the steps of:

comparing a trajectory of the prosthetic component to a trajectory of the spinal instrument; and

viewing the trajectories of the prosthetic component and spinal instrument on the remote system such that the prosthetic component is placed in the identified location of the spinal region along a similar trajectory as the spinal instrument.

7. The method of claim **6** further including a step of rotating a handle of the spinal instrument to change a distraction height.

8. The method of claim **6** further including a step of indicating by visual, audio, or haptic means when the load applied by the spinal region on the spinal instrument is within the predetermined load range.

9. A method of distracting a spinal region comprising the steps of:

inserting a sensored head of a spinal instrument into a spinal region;

locally and electronically measuring a load applied by the spinal region on the sensored head while the spinal region is distracted by the sensored head to a first height, and if the measured load is outside a predetermined load range indicating that the measured load is outside the predetermined load range;

measuring a position of the measured load on the sensored head; and

adjusting the spinal instrument to distract the spinal region to a second height where an electronic load measurement at the second height falls within the predetermined load range.

10. The method of claim **9** further including a step of measuring at least one of orientation, rotation, angle, or position of the inserted sensored head in the spinal region.

11. The method of claim **10** further including the steps of:

moving the spinal instrument to a different location when the position of load applied by the spinal region to the spinal instrument is outside a predetermined position range.

12. The method of claim **11** further including a step of identifying a location in the spinal region for a prosthetic component that falls within the predetermined load range and the predetermined position range.

13. The method of claim **12** further including a step of placing the prosthetic component at the location in the spinal region.

14. The method of claim 13 further including the steps of:
comparing a trajectory of the prosthetic component to a trajectory of the spinal instrument; and
viewing the trajectories of the prosthetic component and spinal instrument on a remote system such that the prosthetic component is placed in the identified location of the spinal region along a similar trajectory as the spinal instrument.

15. A method of tracking alignment and orientation of a spinal region comprising the steps of:
placing a receiver in proximity to a wand where the receiver is in a fixed position and in a line of sight of the wands, where the receiver includes at least two sensors that are configured to measure and transit ultrasonic signals, where the wand includes at least two sensors that are configured to measure and transmit ultrasonic signals;
moving the wand to an anatomic feature on a spine and registering the anatomic feature with respect to the receiver;
retrieving a 3D spine model of the spine having orientation and dimensions corresponding to the registered anatomic feature; and
identifying the location of the registered anatomic feature on the 3D spine model.

16. The method of claim 15 further including a step of attaching a plurality of wands each to a different vertebrae of a spine.

17. The method of claim 15 further including the steps of:
registering a vertebra with a wand;
attaching the wand to the vertebra;
repeating the steps of registering and attaching for different vertebra using the plurality of wands; and
retrieving a 3D vertebra model having orientation and dimensions corresponding to the registered anatomic features of each vertebra.

18. The method of claim 15 further including the step of inserting a sensored head of a measurement instrument between vertebrae of the spine and measuring loading thereon where one of orientation, rotation, angle, or position data is generated corresponding to the sensored head in relation to the vertebrae.

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